



Technical Assessor Information and Guidance Document

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1. Introduction

This document has been prepared for NATA Technical Assessors to serve as resource information.

The purpose of the document is threefold:

- to provide background information about NATA;
- to provide information to assist preparing for and participating in assessments;
- to provide guidance on assessment techniques.

The document is to be used in conjunction with the NATA accreditation documents as specified in Section 3.

When appointed as a Technical Assessor, you will be required to attend a complimentary Technical Assessor Development Program (TADP) provided by NATA Education Advisory Services (NEAS). You will be formally invited to participate in a course when the next one becomes available.

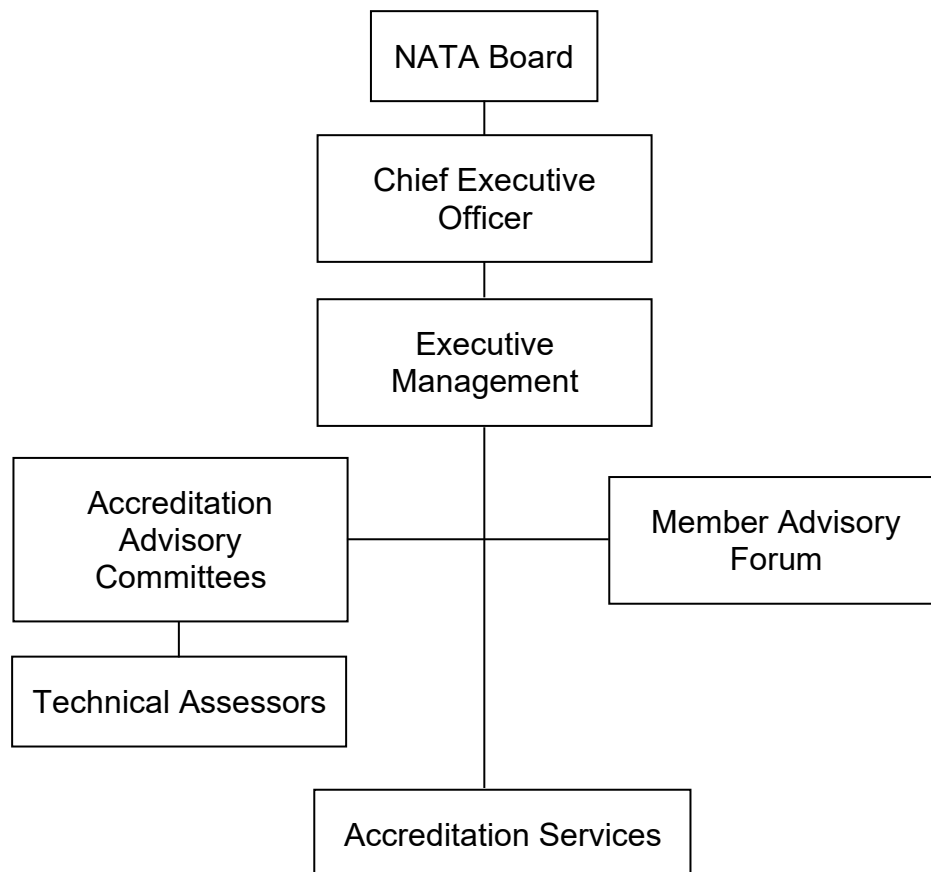
On occasion, you may be invited to participate in an assessment prior to attending a TADP. Should this occur, the NATA Lead Assessor (Accreditation Specialist) leading the assessment will provide you with a briefing beforehand.

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 NATA accreditation documents, or any other matters relating to Technical Assessor development and training by emailing us at technicalassessors@nata.com.au.

2. About NATA

Structure of NATA

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



The NATA Board, Advisory Committee members and Technical Assessors provide their services to NATA on an honorary basis.

NATA Board of Directors

NATA is governed by a Board of Directors, drawn from its members and stakeholders and responsible for overseeing all of NATA's activities.

The Board is supported in the day-to-day running of NATA's activities by the NATA Executive Team.

Accreditation Advisory Committees

The NATA Board receives technical advice from specialist committees that it appoints. These committees are referred to as Accreditation Advisory Committees (AACs). There are a number AACs covering the various activities which NATA accredits. NATA's Sector Managers serve as secretaries to the AACs and are also responsible for the technical oversight of NATA's accreditation programs.

The primary role of the AAC is to provide technical advice for the area of accreditation it covers.

In particular, an AAC may be asked to:

- provide guidance on interpretation of the criteria covered by the relevant accreditation Standard and, where necessary, guidance on the development and review of technical accreditation criteria;
- provide technical and strategic advice relevant to industry, including emerging issues which NATA should be made aware of;
- provide advice on technical issues identified at assessments;
- make recommendations in relation to the accreditation status of a facility;
- recommend new Technical Assessors.

NATA appoints members to an AAC from any interested party following receipt of expressions of interest through a transparent process. The Board is responsible for approving appointments for a defined period based on individuals satisfying the selection criteria.

Technical Assessors

Technical Assessors are selected on the basis of their technical knowledge, expertise and commitment to NATA. They are appointed once the relevant Accreditation Advisory Committee has considered their application following an invitation to join the voluntary panel of assessors.

As a member of an assessment team, the role of the Technical Assessor is to evaluate a facility's technical competence under the guidance of the NATA Lead Assessor.

NATA Lead Assessors

Lead Assessors (Accreditation Specialists) are full-time NATA employees who have been extensively trained to lead assessments.

They are knowledgeable with NATA's assessment processes, the accreditation criteria and serve as the lead for assessment teams. They are responsible for preparing assessment findings, providing guidance to Technical Assessors and follow-up on assessment findings.

NATA's accreditation programs

NATA delivers its accreditation services based on programs. Each program covers a specific standard as defined in the NATA Rules. The following programs are available:

Program	Standard
Biobanking	ISO 20387
Human Pathology	ISO 15189 and NPAAC Standards
Inspection	ISO/IEC 17020
Medical Imaging	RANZCR Standards
Proficiency Testing Scheme Providers	ISO/IEC 17043
Reference Material Producers	ISO 17034
Sleep Disorders Services	ASA Standard for Sleep Disorders Services
Testing and Calibration	ISO/IEC 17025
Respiratory Function	TSANZ Standard for Respiratory Function Laboratories

Memoranda of Understanding

NATA has established a number of Memoranda of Understanding (MoUs).

The most significant MoU is the one with the Australian Government signed in 1988 and reconfirmed in 2024.

There are other MoUs with various instrumentalities and government departments that are industry specific. Where any of these MoUs have particular relevance to your industry, the NATA Lead Assessor will be aware of the policy issues and will provide guidance as required during an assessment visit.

International activities and Mutual Recognition Arrangements

NATA represents Australia's interests, notably in the development of international standards and support to the Australian Government on the establishment of arrangements dependent on conformity assessment activities, for example, Free Trade Agreements.

In the international accreditation forum, Mutual Recognition Arrangements (MRAs) have been established. These govern the acceptance of results from accredited facilities in economies that are signatories to the arrangements. The two arrangements NATA is a signatory of include the Global Accreditation Cooperation Incorporated (previously International Laboratory Accreditation Cooperation - ILAC) and Asia Pacific Accreditation Cooperation (APAC).

NATA's competence as an accreditation body is recognised through its signatory status of ILAC and APAC.

The Global Accreditation Cooperation Incorporated and APAC websites include a list of the economies and the organisations that are party to the arrangements. The listings are under constant revision as more economies and organisations join the arrangements.

All signatories to the MRAs are evaluated periodically against ISO/IEC 17011 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*.

On rare occasions, you may find yourself part of an assessment team being observed by an MRA evaluation team. Should this happen, you will be given guidance and information about what to expect and who will be involved. You should not make any changes to the way you normally participate in a NATA assessment. The evaluation team is there to observe NATA's processes and not to interfere in the outcome of the assessment.

NATA's website and social media platforms

NATA's website (www.nata.com.au) serves as one form of communication with accredited facilities (members) and NATA's Technical Assessors.

NATA also maintains a number of social medial platforms.

The website contains a section titled 'About Us' > 'Our Technical Assessors' which contains information of relevance to Technical Assessors. The NATA website is where all accreditation criteria and guidance documents can be found.

NATA's website portal

The NATA portal is used to exchange accreditation documentation and provides users with notifications of news, eLearning modules and publications (including the accreditation criteria and guidance documents) in their areas of interest. A profile is automatically created for Technical Assessors.

As an interface between the Technical Assessor and NATA the portal allows:

- safe and secure submission of documents;
- the exchange of large sized files outside email;
- details on assessments which you have been appointed;
- notifications to the receiving party when 'job' related documents are uploaded to the portal;
- access to targeted communications, information and publications including email and dashboard notifications of any new or modified NATA publication available via the portal.

By accessing or using the portal, you agree to the Terms and Conditions which can be accessed via the NATA website www.nata.com.au. A reference guide for use of the portal is also available on the website.

3. The accreditation documents

NATA accreditation is based on the evaluation of a facility's technical competence against the criteria specific to each accreditation program. These are detailed in the NATA Accreditation Criteria (NAC) packages available from the NATA website and the NATA portal. Technical Assessors will automatically be subscribed to the relevant NAC package on the portal.

Each NAC includes the following documents:

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

In addition to alignment with an accreditation program, where relevant a NAC is also aligned with a specific industry (e.g. Agribusiness, Food & Beverage, Legal, Materials etc).

Note: The guidance documents included in the NACs do not specifically serve as accreditation criteria.

The General Documents, Criteria, Guidance and Forms are applicable to all accredited and applicant facilities, while the Specific Criteria, Guidance and Forms are applicable to particular industries or discrete technical disciplines.

NATA Procedures for Accreditation

This is an informative document applicable to all accreditation programs and explains NATA's accreditation processes.

The NATA Rules

The Rules take precedence over all other NATA documents and detail NATA's constitution and regulations. They define the conditions for maintaining accreditation and the rights and obligations of NATA members.

Accreditation program standard

The NAC references the relevant ISO or industry standard applicable to the accreditation program.

NATA General Accreditation Criteria (GAC)

These documents describe the general accreditation criteria applicable to an accreditation program and include the relevant Standard Application Document (SAD) (e.g. *ISO/IEC 17025 Standard Application Document*). The SAD provides interpretative criteria and recommendations for the application of the relevant standard.

NATA Specific Accreditation Criteria (SAC)

For particular industries or discrete technical disciplines, NATA additionally publishes SACs and associated Appendices and Annexes where relevant.

NATA General Accreditation Guidance (GAG) and Specific Accreditation Guidance (SAG)

The GAG and SAG documents provide additional guidance which do not serve as accreditation criteria, however provide best practice recommendations. These documents include for example:

- general and reference equipment tables that provide guidance on calibration and checking intervals and the associated procedures;
- documents providing interpretative information to assist facilities in relation to particular technical matters.

NATA General Accreditation Forms and Specific Accreditation Forms

These documents include checklists, worksheets and site notification forms.

Prior to any assessment, you should ensure you have the latest accreditation documents available and are familiar with them.

4. Technical Assessors

Recognised technical expertise and experience

NATA invites individuals who have the required professional / technical experience and personal qualities to join the panel of Technical Assessors.

Individuals NATA invites may come from, but not limited to:

- academic institutions;
- research establishments;
- public and private facilities engaged in activities NATA accredits.

Technical Assessors are invited on the basis of their:

- professional / technical expertise;
- experience and practical application or familiarisation with the activities NATA accredits;
- where relevant, qualifications;
- personal skills and attributes, for example:
 - ability to critically evaluate;
 - be objective;
 - work as a member of a team;
 - good written, aural and oral communication;
 - ability to maintain confidentiality.
- commitment to NATA and the accreditation process.

Individuals are asked to complete the appropriate form provided by NATA prior to being considered and approved as a Technical Assessor.

This form includes a confidentiality agreement and a list of the activities nominated by the individual which they are competent to assess.

It is NATA's expectation that Technical Assessors have obtained the necessary authorisation from their employer to be a member of the panel of Technical Assessors.

Technical Assessor performance and appointment is reviewed periodically and notably after participation in an assessment. Appointment may be discontinued, for example, due to unsatisfactory performance, breach of confidentiality, etc.

Technical Assessors are requested to actively inform NATA of changes to their personal details (e.g. contact numbers, change of employer, changes to competencies etc). NATA will also periodically request for this information. It is important that you respond to such requests in order for your Technical Assessor status to remain current. Further, keeping these details current assists NATA with assessment team selection.

Technical Assessor Development Program (TADP)

Attendance at a TADP training course provided by NATA Education Advisory Services (NEAS) is a mandatory aspect of your commitment as a Technical Assessor. The course is general in nature and applicable to all Technical Assessors irrespective of the accreditation program.

The course is scheduled periodically and is provided free of charge (excluding travel and accommodation if they are required).

The course covers:

- the role of the Technical Assessor;
- the role of the NATA Lead Assessor;
- preparation for an assessment;
- conduct of an assessment;
- tips and hints on assessing skills.

On appointment as a Technical Assessor, you will be automatically invited to attend the next TADP course in your locality or via a virtual platform. If you are not able to attend, it is expected you advise NATA by emailing technicalassessors@nata.com.au so attendance at another session can be scheduled. Should you not attend a TADP within the first 2 years following your appointment your status as a Technical Assessor will be reviewed. Mitigating factors such as provision of TADP sessions in your locality, apologies received from you for not being able to attend an invitation to a course, etc will be considered as part of this review.

TADP course dates and locations can be provided by contacting NATA Education Advisory Services on 1800 621 666 (free call) or by emailing info@neas.com.au

Experienced Technical Assessors are also welcome to attend a TADP as a refresher by contacting NATA.

A Technical Assessor may be called upon to participate in an assessment before it is possible to attend a TADP. In such cases, the NATA Lead Assessor will provide appropriate guidance and direction.

On occasion, NATA may prescribe additional mandatory training requirements for Technical Assessors.

Time commitment

Technical Assessors are completely free to accept or decline any invitation to participate in an assessment. Prior to accepting an invitation, you should give due consideration to the time necessary.

Generally, Technical Assessors are invited to participate in two to four assessments per year. Most assessments occur over one day, however, some may extend for longer periods dependent on the activities to be reviewed.

Apart from the assessment day, there will be a need to dedicate some time preparing for the assessment. Further, you may also be asked to review a facility's response to specific assessment findings post assessment.

Occasionally you may be asked to travel interstate, to country locations or on the very rare occasion overseas. This will require a greater time commitment.

Conflicts of interest and confidentiality

Potential conflicts of interest must be advised to the NATA Lead Assessor when considering whether to accept an invitation to participate in an assessment. The need for confidentiality in relation to any assessment you participate in is also paramount.

The form completed when first invited to join the assessor panel includes a commitment to declare any conflicts of interest regarding an organisation you may be invited to assess. Examples of conflict of interest include but are not limited to:

- company alliances and commercial interests in a facility;
- commercial arrangements (e.g. client/supplier relations);
- consultancy arrangements (current and/or past);
- close personal associations (family and/or friends).

Prior to NATA confirming your participation in any assessment, you will also be required to again formally declare:

- any conflict of interest with the facility to be assessed;
- compliance with the NATA Rules;
- compliance with NATA's privacy policy;
- to hold all information in relation to the assessment confidential.

During the course of an assessment, if you become aware of any conflict of interest, you are expected to raise this as soon as possible with the NATA Lead Assessor.

When preparing for an assessment, the facility is also given the opportunity to consider all proposed Technical Assessors and to advise NATA of any conflicts of interest.

All information shared with you or obtained relating to an assessment remains strictly confidential.

This includes:

- all arrangements including the name of the facility to be assessed and other Technical Assessors involved;
- briefing documentation provided;
- discussions during the assessment, findings and outcomes;
- information about the facility's operations obtained during the course of the assessment that would otherwise not normally be available to you.

Breaches of confidentiality are viewed very seriously and as a minimum will jeopardise an individual's ongoing participation and recognition as a NATA Technical Assessor.

Some hints for maintaining confidentiality include:

- remembering that all matters and information associated with an assessment is privileged;
- preventing others access to the briefing information provided to you:
 - if held electronically, then ensuring your electronic device is protected (e.g. password protected);
 - if provided in hardcopy, then storing it in a secure location not accessible to others. Be particularly vigilant at airports, whilst travelling to and from an assessment and in your assessment accommodation;
- using the portal as the primary source of information exchange between yourself and NATA;
- keeping your portal log-in details and any other passwords secure. Do not share your passwords with anyone or in any way publish them or write them down. Never send a password through email or reveal over the telephone. Do not let anyone see you type your password;
- avoiding the use of unencrypted email to transfer personally identifiable or sensitive information;
- using an email address that is not accessible by others (e.g. a generic email accessible by other people within your organisation, or a shared email account with a family member);
- strictly not discussing any information about the assessment with others;
- during the assessment not removing any hardcopy information or capturing information by electronic means (e.g. photos with mobile phone);
- at the completion of the assessment, deleting information if held electronically on any device or returning any hardcopy briefing information to the NATA Lead Assessor for disposal.

In the event that information security has been compromised inform a member of NATA staff immediately. NATA is committed to ensuring the security of information in its possession. In order to support this commitment an information security management system has been established in accordance with ISO/IEC 27001 *Information security, cybersecurity and privacy protection - Information security management systems - Requirements* .

Gifts and meals

The acceptance of dining invitations and gifts may be of concern due to potential undue pressure or risks to maintaining impartiality.

The NATA Lead Assessor will provide guidance as to what is acceptable, but the following points are offered:

- dining invitations or gifts can be considered as a gesture of hospitality if offered by a facility;
- under no circumstance should meals and gifts be requested of, or expected of a facility;

- the provision of lunch by the facility is an acceptable time and cost-effective business practice;
- occasionally company souvenirs are provided (e.g. corporate mugs, caps, etc).

Particularly when travelling overseas:

- familiarise yourself with usual business practices and culture as to what is acceptable;
- small gifts may be given as a token of appreciation for your time and effort;
- as a sign of hospitality, facility staff may also offer to take you for evening meals, or on local guided tours during any spare time.

Provided the above are not excessive then they are acceptable. If you are in any way uncomfortable, discuss it with the NATA Lead Assessor or gracefully decline.

Conduct and ethics

As representatives of NATA, Technical Assessors are expected to conduct themselves in a professional and courteous manner and observe the following standards of behaviour:

- comply with all Laws;
- comply with any reasonable (and legal) instruction from NATA;
- be impartial, honest and fair in dealings with NATA staff and clients;
- treat others in a non-discriminatory manner with proper regard for their rights and dignity;
- respect NATA's position of political neutrality.

If you have any questions or believe you have been exposed to discriminatory or inappropriate behaviour whilst conducting NATA business, please contact NATA's Chief People Officer or Head of Accreditation Services 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 and volunteers feel safe and valued.

It is the responsibility of the NATA Lead Assessor and the Technical Assessor to conduct assessments in accordance with NATA's Work Health and Safety Policies to protect both themselves and others.

Drug and alcohol testing at the workplace has become common practice.

NATA expects assessment team members to be free from the influence of any drugs and alcohol at all times while performing an assessment regardless of the location. This includes while travelling to the facility's premises or NATA.

When conducting an assessment, you are first obligated to comply with the facility's safety requirements. The following should be adhered to at all times:

- sign in and out as per the facility's protocol;

- do not wander around the facility's premises unaccompanied unless your contact person has given permission;
- attend any induction as directed;
- if you recognise any potential hazard, or should a safety incident occur, it must be reported to the facility immediately;
- all requests from the facility's safety / emergency personnel must be followed;
- compliance with the drug, alcohol and COVID policies and procedures, including the need for testing as directed;
- Personal Protective Equipment (PPE) is to be worn as required.

Apart from complying with the facility's safety requirements for reporting an accident or injury, also bring the matter to the NATA Lead Assessor.

Prior to an assessment, NATA gathers information from the facility in relation to health and safety requirements and Technical Assessors are made aware of these. If you are unable to comply with any requirement then you should advise the NATA Lead Assessor which may include declining participation in the assessment.

Where drug and/or alcohol testing will be performed, there is no obligation for the results to be disclosed to NATA unless the individual provides consent to do so.

Privacy policy

NATA respects and upholds the rights of individuals to privacy protection under the Australian Privacy Principles contained in the Privacy Amendment (Enhancing Privacy Protection) Act 2012. 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 NATA manages 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 and mobile phone numbers, home address, home telephone and personal mobile phone numbers, e-mail 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 Mutual Recognition Arrangement (MRA) evaluations of NATA. All individuals having access to the information 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 a Memorandum of Understanding or similar formal agreement.

From time to time, NATA receives requests from MRA partners for technical experts to assist in their assessments. With your express consent, information may be disclosed to these accreditation bodies to enable them to contact you should you be willing to participate.

Insurance

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

Insurance	Cover
Public Liability and Professional Indemnity	Technical Assessors are indemnified when performing tasks on behalf of NATA.
Group Personal Accident	This insurance provides cover anywhere in the world when engaged in voluntary work authorised by and under the control of NATA. This includes travel to and/or from training/work.
Corporate Travel	Technical Assessors are covered when on authorised business travel from the time the person leaves their residence or business and is continuous for a full 24 hours until the assessor's return. This insurance covers the following categories up to pre-set limits: death & disablement, weekly injury benefit, overseas medical expenses, additional/cancellation/curtailment expenses, luggage, personal effects, travel documents, additional money cover, personal liability, kidnap & ransom, loss of deposits, legal costs, extra territorial workers compensation.
Rental Vehicle	<p>NATA has insurance to cover the excess payable for rental vehicle damage. Therefore, you should not accept the Excess Reduction Insurance, or the Personal & Baggage Insurance offered by car rental depots and/or agencies if asked to do so.</p> <p>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).</p> <p>All accidents involving rental vehicles must be reported immediately to the car rental depot and/or agency. A copy of the accident report and bill of repairs should also be sent to the NATA Lead Assessor.</p>

NATA does not provide insurance to cover private motor vehicles for Technical Assessors. If using your own vehicle during a NATA assessment it is expected that you maintain your 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, contact your nearest NATA office immediately for information and assistance with the claim process.

Consultation for legal matters

Technical Assessors should be aware that the NATA assessment process and/or assessment findings can become the subject of legal proceedings. Consequently, 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, accredited facilities and/or an assessment that you participated in, please immediately contact NATA's Head of Compliance and Governance.

Some guidance is provided below:

NATA's accreditation processes

It is not appropriate under any circumstance to comment on any NATA policy or procedure 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 a general discussion with anyone.

Assessment visit matters

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

On technical issues, it is judicious to keep your responses within your scope of expertise/knowledge.

It is also inappropriate to comment on another Technical Assessor's performance or findings.

Outside of a tribunal/court environment you are obliged to continue to maintain strict confidentiality about any assessment you participated in.

Cultural issues

You may be invited to participate in an assessment where cultural differences may be encountered, for example:

- overseas assessments;
- assessments where the parent company is based overseas.

NATA will provide you with advice on local manners and etiquette where we are aware of these. However, you can also follow the lead provided by the staff of the facility. If you have any uncertainty, discuss it with the NATA Lead Assessor.

In particular, be sensitive, respectful and mindful of the following:

- introduction formalities (e.g. 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);
- use of English language:
 - proficiency of facility staff;
 - avoiding use of vernacular terms and 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 (e.g. avoid talking directly towards interpreters);
- senior/subordinate staff relations;
Note: Other cultures often place far more emphasis on seniority/respect than is normal in Australian business culture. Be aware that you are in a significant position of authority and will accordingly be treated with a degree of deference and respect.
- dining preferences and etiquette;
- dress code (e.g. tends to be more formal);
- religious observances;
- general conversation topics (e.g. refrain from raising sensitive world topics, and take care when making observations about local issues);
- avoid comparing processes and systems (e.g. Australian versus local way of doing things).

5. Assessment arrangements

General overview

Prior to making necessary transport and accommodation arrangements, NATA will discuss any options and needs with the Technical Assessors.

NATA arranges and covers all reasonable costs associated with the conduct of assessment activities including:

- accommodation and meals;
- travel;
- insurance.

It is NATA's policy that arrangements are made at an acceptable standard yet in the most economical manner.

NATA provides or arranges all transport. If, in order to perform an assessment, an overnight stay away from home is required, accommodation is reserved.

Confirmation of arrangements are sent prior to the assessment, and it is advised that you carry a copy of the travel itinerary to provide evidence of bookings and confirmation of payment arrangements.

If you use your own car, a distance-based allowance is paid.

NATA asks all Technical Assessors to:

- exercise good judgment with respect to travel expenses;
- check for accuracy of bills and other documents before authorising.

There may be occasions where you may be out-of-pocket for expenses. A form is provided to you to record these and to attach your receipts (tax invoices) for NATA to reimburse you.

The following is a summary of NATA's current travel policy and is subject to change from time to time.

Expense claims

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

- parking fees and road tolls;
- petrol expenses (only when using rental cars, not for private car use);
- kilometre rate (for private vehicle use only);
- meals paid for by you;
- emergency travel needs (e.g. personal toiletries, etc if your luggage fails to arrive at your destination with you);
- incidentals (to a maximum daily value).

Tax invoice receipts must be obtained to substantiate all expenses which you should attach to the claim form and forward to the NATA Lead Assessor as soon as possible on your return from the assessment.

For small amounts under \$10.00 (e.g. road tolls, parking usually paid by cash) receipts are not normally required.

Air travel

NATA's policy for air travel is to purchase tickets at the lowest cost consistent with good business practice.

For domestic travel, economy class airfares are used.

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

Individuals may not insist on an airline purely to accrue frequent-flyer points or based on personal membership status. NATA's main criteria for airline preference are geographical coverage, comfort and safety for staff and volunteers, consistency in on-time flights and competitive prices.

Technical Assessors, Board Members, Committee Members and NATA staff are booked on flights with the airline which provides the *Best Fare of the Day* within a 2-hour window of desired travel time.

When changes to travel plans are needed which require either cancellation or revision of reservations already made, notify NATA as soon as possible.

Accommodation and meal expenses

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

A single room in a business class hotel/motel is the corporate standard.

When departing the hotel, check the account carefully to ensure the expenses incurred are correct. All expenses for which NATA is responsible will be charged back to NATA. You are however responsible for any personal extra expenses such as mini-bar consumption, in-house movies, lengthy personal phone calls, etc and these are to be paid for at the time you check out.

All meals and reasonable expenses will normally be paid for by the NATA Lead Assessor who is accompanying you.

If you are dining alone, NATA will cover the cost of meals either by you submitting a tax invoice with your claim form or by charging the expenses back to your room if dining in the hotel.

Where someone personal will be accompanying you, any additional charges incurred will be required to be covered by you. Please discuss with NATA your intention to bring someone prior to the assessment so any necessary arrangements can be considered.

Rental cars

Car rental will only be used when other means of cheaper or convenient transportation are not available. 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.

Where the use of a rental car by a Technical Assessor is necessary, NATA will make the booking. Ensure you are clear on the pick-up, drop-off and other instructions according to the booking confirmation provided to you. In relation to rental insurance, refer to the Insurance section above.

When using a rental car, if possible, fill it with petrol before returning it as the amount charged for petrol by the car rental companies is far in excess of the normal price. Petrol expenses can be claimed back on the expenses claim form provided to you.

Use of private car

Under some circumstances, it may be more cost-effective or convenient for a Technical Assessor to use their private car for transport.

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

The expenses claim form should also be used for any other incurred costs, for example, parking fees and road tolls.

Technical Assessors using their own car must carry adequate car insurance as NATA does not insure a Technical Assessor's private vehicle.

Whether using a rental or private car, parking infringements, speeding fines and other driver related traffic offences incurred by Technical Assessors will not be reimbursed by NATA.

Transport eTickets

Transport eTickets (e.g. Taxi, Uber) are provided as necessary and can be provided in two ways:

- physical eTicket vouchers which are used the same way as a credit card but are valid for one trip only. Enough vouchers will be issued to cover an entire journey.
- eTicket Digital pass can be issued for an entire journey with a designated number of trips. These will be provided by email or SMS and can be added to an Apple or Google Pay wallet.

On the rare occasion that an eTicket does not work, NATA will reimburse any out-of-pocket expenses incurred (refer to section titled **Expense claims** above).

6. Roles and responsibilities of the assessment team

Role and responsibilities of NATA

Prior to the assessment NATA will:

- select the assessment team;
- liaise with the Technical Assessor(s) and facility staff;
- clarify potential conflicts of interest between the Technical Assessor(s) and the facility;
- arrange and confirm the assessment logistics including date, time and duration;
- make appropriate travel arrangements and bookings;
- conduct the document review;
- prepare the briefing material, assessment program (timetable), the sample of activities to review and specifically those to be witnessed;
- provide the Technical Assessor(s) with background briefing including previous assessment findings where available, any relevant documentation from the facility as necessary, form(s) to record assessment findings, travel arrangements and bookings as necessary, expenses claim form and any other information as appropriate.

During the assessment the NATA Lead Assessor:

- provides direction and answers questions regarding NATA's assessment processes, accreditation criteria, precedents, etc;
- arranges the pre-assessment team briefing to clarify any matters or queries;
- facilitates the assessment opening meeting;
- coordinates the evaluation of the facility's technical competence and reviews the management system;
- follows-up on issues raised at previous assessments (where appropriate);
- supports and assists the Technical Assessor(s);
- prepares the draft (interim) report on assessment following the final team meeting;
- presents the assessment team's findings to the facility staff at the closing meeting.

After the assessment the NATA Lead Assessor:

- follows-up on any required action arising from the assessment which may include providing a response back to the facility;
- prepares the final (confirmed) report on assessment;
- coordinates the review of the facility's response to any assessment findings which may include Technical Assessor input;
- coordinates the confirmation of the facility's accreditation status once all assessment findings have been closed.

Role and responsibilities of the Technical Assessor

Prior to the assessment you must:

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

During the assessment you will need to:

- under the direction of the NATA Lead Assessor, review the competence of the facility to perform the activities for which accreditation is held or being sought;
- gather and record objective evidence using the form provided for this purpose;
Note: Ensure your records are accurate and legible for discussion with the NATA Lead Assessor.
- be aware of the time constraints and the importance of keeping to the assessment program;
Note: 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.
- be aware of the importance of teamwork;
- keep in touch with and seek direction and guidance from the NATA Lead Assessor during the course of the assessment.

After the assessment ensure you:

- continue to maintain confidentiality;
- as requested, provide the NATA Lead Assessor with feedback on any responses from the facility to assessment findings in a timely manner;
- if relevant, complete and return the expenses claim form together with receipts and any unused Transport eTickets;
- return any hardcopy briefing material to the NATA Lead Assessor after you have finished with it and/or securely delete any electronic versions held.

It is important to not place yourself in a situation where you are consulting to the facility and, hence compromising the assessment.

7. Assessments

The purpose of an assessment

An assessment involves the evaluation of objective evidence to confirm that a facility:

- satisfies the accreditation criteria;
- is competent to perform the activities for which accreditation is held or being sought as covered by the scope of accreditation.

During an assessment it is essential to remember that there may be different ways to satisfy the accreditation criteria, thus it is important to not impose personal opinions / preferences as to how things should be done.

Remember that an assessment is “*a fact-finding mission, not a fault-finding safari*”.

Assessment types

The main types of assessments that may be conducted by NATA include:

Assessment	Accreditation status of facility	Performed by and coverage
Initial assessment	Applicant facility yet to achieve accreditation	Is performed by a NATA Lead Assessor and one or more Technical Assessors to evaluate the facility against all of the accreditation criteria.
Surveillance visit	Accredited facility	Is a scheduled on-site assessment performed by a NATA Lead Assessor mid accreditation cycle. Surveillance visits for the Sleep Disorders Services and Respiratory Function accreditation programs are an in-office activity. Surveillance visits for the Inspection program may occasionally include a Technical Assessor. The focus of the visit is to review the facility’s management system and selected technical elements.
Reassessment	Accredited facility	Is a scheduled on-site assessment performed by a NATA Lead Assessor and one or more Technical Assessors at the end of the accreditation cycle. The focus of the visit is to review the facility’s technical activities and selected management system elements.

Assessment	Accreditation status of facility	Performed by and coverage
On-site variation visit or desk-top review	Accredited facility	Non-scheduled assessment performed by a NATA Lead Assessor and one or more Technical Assessors where necessary to consider a request for addition(s) to a facility's scope of accreditation.
Follow-up assessments	Accredited facility	Non-scheduled assessment performed by a NATA Lead Assessor and one or more Technical Assessors where necessary to review significant issues identified at the previous assessment.

8. Preparing for assessments

Selection of Technical Assessors

Assessments always consist of a NATA Lead Assessor.

For assessments requiring Technical Assessors, the number selected will be dependent on the breadth of the activities offered by the facility needing to be assessed and the scope of expertise of the individual Technical Assessors.

Technical Assessors are selected to participate in an assessment based on:

- their technical expertise and experience;
- the tests, inspections and/or other services performed by the facility;
- their assessment history;
- their geographic location and that of the facility;
- avoidance of conflicts of interest;
- both their and the facility's agreement.

Document review

In preparation for an assessment, the NATA Lead Assessor may conduct a document review. This involves a review of the facility's management system and related documentation.

The purpose of the document review is to:

- confirm that the facility has considered and addressed the accreditation criteria;
- provide the NATA Lead Assessor with both an understanding of the facility's operation and an opportunity to identify any specific areas that will need specific review during the on-site assessment.

Assessment briefing information

Technical Assessors are provided with briefing information, referred to as the 'Briefing Notes', prior to the assessment.

The documentation includes:

- information on the purpose of the assessment;
- a copy of the current scope of accreditation (other than for initial assessments);
- copies of the assessment reports for the previous accreditation cycle and any correspondence relating to matters needing to be followed-up during the current assessment;
- relevant information on the facility (e.g. current staff, activities performed, methods/procedures used, equipment, listing of proficiency testing, etc);
- an assessment program (timetable);

- an assessment sampling plan (identifies those activities falling under the scope of accreditation to be specifically reviewed);
- copies of any relevant procedures or records deemed necessary to review prior to the assessment;
- an *Assessment Worksheet* (which may include details of the document review performed by the NATA Lead Assessor);
- a record sheet(s) to record objective evidence.

What to do before an assessment

To prepare for a visit:

- review the briefing information as soon as practicable;
- as necessary, refresh your knowledge of the accreditation criteria and any relevant standards or test methods;
- review the activities performed by the facility (scope of accreditation or other information provided) and advise NATA:
 - immediately if you identify an activity you are not able to assess (this however should not occur as your expertise / experience would have been clarified before your appointment to the assessment);
 - of any specific activity you wish to witness which has not been included in the assessment sampling plan provided.

9. Conducting assessments

The overall flow of assessments follows a consistent pattern involving five sequential phases:

1. Team briefing;
2. Opening meeting;
3. Evaluation of the facility against the accreditation criteria and determination of competence for the activities proposed to be covered, or currently covered, by the scope of accreditation;
4. Final team meeting;
5. Closing meeting.

Team briefing before the assessment

Prior to the assessment, the NATA Lead Assessor will normally gather the assessment team for a team briefing. The meeting may occur:

- on the morning of the assessment; or
- the evening before if the assessment team needed to travel; or
- on occasion by telephone at an appropriate time.

The purpose of the meeting is to:

- introduce the team members to one another and specifically the role of the Lead Assessor;
- confirm the assessment timetable, assessment sampling plan and allocation of tasks for each assessment team member;
- advise of any changes which have occurred to the facility since the issue of the briefing information;
- clarify any queries the Technical Assessors may have.

Opening meeting

The NATA Lead Assessor will commence the assessment with an opening meeting with the assessment team and key facility staff.

The meeting will:

- introduce the assessment team and facility staff;
- explain the purpose and scope of the assessment;
- reconfirm the assessment timetable including lunch and other breaks;
- reconfirm the proposed or current scope of accreditation including any changes to be made;
- reconfirm the arrangements made for witnessing of activities;
- confirm the availability of facility staff to be involved and any time constraints on them;

- explain how any assessment findings will be raised and how they will be coded;
- reconfirm the confidentiality of the assessment and its outcome;
- confirm that a room or quiet area has been set aside for the assessment team's use;
- clarify any queries the facility may have.

Assessment of the facility and determination of competence

Following the opening meeting, the evaluation (assessment) of the facility will commence to confirm:

- that the accreditation criteria are satisfied;
Note: The assessment also determines whether the facility is complying with its own documented processes (which must satisfy the accreditation criteria).
- that the facility is competent to perform the activities covered, or to be covered, by the scope of accreditation.

Generally, the NATA Lead Assessor and Technical Assessor(s) work together and support each other. However, the review of the management system is mainly the Lead Assessor's responsibility.

It is important throughout the assessment that the assessment team limits its review to only those activities covered by the facility's scope of accreditation and the accreditation criteria.

The following, which are broadly reflected in the accreditation standards, should be taken into account during the assessment:

- availability of documented processes;
- control of data and information management.
- supervision and technical control of the facility;
- the personnel, including their competency, authorisation(s) and monitoring;
- the suitability and monitoring of the premises / environmental conditions;
- availability, maintenance and calibration of equipment;
- externally provided services and products;
- review of requests, tenders and contracts for services offered;
- handling of test / calibration / inspection items;
- validation and verification of methods including, as relevant, estimation of measurement uncertainty, metrological traceability and sampling activities;
- processes for ensuring the validity of results;
- reporting of results.

As individuals, Technical Assessors may differ in their approach when conducting assessments, however they must always:

- work under the direction and guidance of the NATA Lead Assessor;
- keep within the scope of their assigned tasks, including the assessment timetable provided;
- remain objective and impartial when gathering evidence, including the need to probe further as necessary, through discussions, with facility staff, witnessing activities being performed and when reviewing documentation;
- record their evidence on the form provided in order to support any assessment findings (i.e. whether there is compliance, non-compliance or an opportunity for improvement);

Note: The evidence recorded should include sufficient detail, for example, what was reviewed (reference / identifier of documentation, method, equipment, worksheet, etc), who was spoken to, the “sample size”, etc.

During the assessment the range of activities to be discussed with facility staff and/or witnessed, should be as per the plan provided to you prior to the assessment by NATA. Conducting vertical audits does allow a natural review of workflows to occur while at the same time covering many of the accreditation criteria.

The following topics provide some guidance on key matters to assess. Remember though the NATA Lead Assessor will provide guidance and that they are the “go to” person during the assessment.

Common elements

There are many processes which may be considered common or relevant across various activities performed by the facility being assessed. You should be mindful of these and not draw any conclusions on processes without considering how they apply across all activities. Some of these processes include:

- control of documentation, for example:
 - is there a process for approving documents prior to issue by authorised personnel?;
 - are procedures and forms appropriately identified and the latest versions only available and used by staff?
 - how are required documents updated?
 - is there a process for updating to the latest version of standard methods?
- availability and management of data / information, whether paper based or held electronically, relating to the activities performed.

Note: The data should be sufficiently detailed to allow a ‘reconstruct’ of the activity (whether in part or full).

Data / information may relate to, for example:

- sample receipt and identification;
- instruments printouts or handwritten observations;
- completed worksheets, calculations, including correction (e.g. authorised);

- equipment used, including reagents, consumables, reference standards etc;
- procedures or standard methods followed;
- quality control data proficiency testing where relevant;
- checks (e.g. data transfers) and reviews performed.

Supervision and technical control of the facility

This is one of the important activities to review, notably as management is ultimately responsible for setting directions, including communicating these, and is accountable for the outputs of the facility.

It should be remembered that matters of concern identified with the facility's operations should not necessarily be attributed to individuals, but instead potential failure(s) in the systems and monitoring processes adopted and management's role in overseeing these.

Staff training and competence

During your discussions with staff and witnessing of activities being performed, you should establish whether they:

- are appropriately trained, understand their responsibilities / role and are authorised to perform the activities for which they have been deemed competent;
- are supervised and monitored;
- understand the principles and limitations of the methods and procedures adopted.

Facilities and environmental conditions

Assessment of these should include:

- appropriateness to perform activities (e.g. "fit for purpose", lighting, ventilation, access control, contamination issues etc);
- controlling and monitoring as necessary, which will include the availability of appropriate equipment.

Equipment

Equipment may include but not be limited to measuring instruments, measurement standards, reference materials and data, reagents and consumables, software, auxiliary apparatus etc.

During the assessment, ensure that:

- all necessary equipment is available (or the facility has access to it) and it satisfies needs (for the activities performed);
- equipment is appropriately handled, stored and maintained, including a calibration / check schedule established as necessary;
Note: Where calibration is necessary, it is to be performed in accordance with NATA's *General Accreditation Criteria: Metrological Traceability Policy* and NATA's *General Accreditation Criteria: Equipment Assurance, in-house Calibration and Equipment Verification*.
- operating instructions are adequately documented;
- measures are in place to prevent:
 - accidental adjustments that could invalidate results;
 - use of equipment that is damaged or requiring calibration / checks.

Requests, tenders and contracts

Procedures should be in place which ensure that the facility understands the work requested from customers, that resources are available and that the appropriate methods / procedures are selected. Additional things to consider are the processes adopted when changes to the request are necessary or when reporting to a specification is required.

Handling of items or samples (e.g. for testing / calibration)

The handling of items / samples, including their tracking / traceability to ensure integrity of data is paramount. Some aspects to focus on include receipt of items, suitability, storage (including protection), retention, identification and labelling, sub-sampling and disposal.

Methods and procedures

These should be reviewed to ensure they:

- are documented clearly, in sufficient detail and the latest version available;
- are appropriate to meet the customer's requested services;
- have been verified (including evaluation of measurement uncertainty as relevant) if they are published peer reviewed or standard methods;
- have been validated (including evaluation of measurement uncertainty as relevant) if they are modified standard methods or developed in-house.

Ensuring the validity and reliability of test results

Two main aspects need to be considered for monitoring results including:

- internal measures adopted (e.g. use of quality control materials, reference materials, comparison of results using alternative instruments, retesting, etc)
- comparisons performed with other laboratories (e.g. proficiency testing).

For both aspects, consider the data generated, the facility's monitoring processes and the action taken when the analysis of the data is not within predefined acceptance criteria.

Reports

The criteria for reporting results are included in the relevant accreditation standard. Apart from the information included in reports, attentions should also be given to:

- use of the NATA endorsement (refer to *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation*) and claims made to accredited activities (e.g. inclusion of results of non-accredited activities);
- how results are expressed (e.g. units, rounding, reporting of measurement uncertainty, compliance statements, decision rules etc);
- reporting of preliminary / interim results;
- control measures in place for issuing electronic reports;
- corrections to reported results (e.g. amended reports);
- processes for reporting results verbally;
- handling result enquiries received from customers.

Management system

The NATA Lead Assessor is responsible for assessing the facility's management system, however, they may request you to review some aspects as necessary. Key areas of a management system include:

- control of documents;
- actions to address risks and opportunities;
- improvements;
- corrective actions;
- internal audits;
- management reviews.

The NATA Lead Assessor is also generally responsible for reviewing the facility's complaints processes despite these not specifically forming part of the management system (as defined by the accreditation standards).

Clarifying assessment findings before drawing conclusions

The process of gathering information during the assessment will uncover events or activities which seem at variance with the requirements for accreditation or the facility's own procedures.

It is important to remain objective, not be clouded by your own views and to note that a facility will never be required to change its work practices based on your own personal opinion.

You should pause, review the information gathered and ask yourself a few questions before coming to any conclusions:

- do you have all the facts?
- 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?
- is what has been observed wrong or just different to your expectation?
- have you understood the facility's processes?
- can an explanation be provided?
- is the issue isolated or has it occurred more than once indicating a more systemic issue?
- did the facility's own processes identify the issue?

Confirming that a non-conformity exists

Before confirming a finding is indeed a non-conformity (i.e. a condition for accreditation), a twofold test needs to be applied to the evidence gathered:

- can the apparent non-conformity be expressed in words from NATA's Accreditation Criteria (NAC) or from the facility's own documented processes?
- is there specific evidence to support the non-conformity which has been gathered and written down (e.g. observations, worksheet entries, equipment records, test reports, etc)?

During the assessment while engaging with facility staff, it is important to remember to not make any conclusions regarding your findings. It is at the final assessment team meeting where findings will be discussed with the NATA Lead Assessor and decisions made, including the need if necessary for further information to be collected or referral of any matter for additional advice.

Using AI tools like ChatGPT for assessments is discouraged, as it may violate NATA's privacy and confidentiality policies. Furthermore, AI may not provide reliable information, and if there is any uncertainty regarding the technical validity of an issue, it should be referred to the NATA Lead Assessor, who will determine the appropriate course of action.

Opportunities for improvement vs consultation

The identification of opportunities for improvement during assessments, and the communication of these findings to facilities, are important elements of the

assessment process. However, care must be taken to ensure the assessment team's input is relevant, balanced and impartial.

It is important when communicating opportunities for improvement that provision of specific advice (verbal and written report) is avoided, and NATA is not perceived as providing a consultative service. Specific advice (i.e. on matters other than compliance) affects impartiality since the activities for which advice is being provided will eventually be reviewed again by NATA (and review of NATA's own "work" is not impartial).

Final assessment team meeting

The purpose of this meeting is to enable the NATA 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. During the meeting, the NATA Lead Assessor will ask you to complete, if not already done, the form provided to you as part of the briefing package to record your assessment findings. The evidence you record should be:

- sufficiently detailed to support any findings to be raised in the assessment report to be prepared by the NATA Lead Assessor;
- written legibly (if handwritten) and phrased appropriately.

In the relatively short time that is available for this team meeting, the following tasks must be completed under the direction of the NATA Lead Assessor:

- confirm that sufficient evidence has been gathered by the assessment team collectively to determine that the accreditation criteria have been satisfied or otherwise;
- each member of the team must table the evidence they recorded in support of their conclusions;
- any findings to be raised in the assessment report must be graded (coded) and assigned to the relevant clause / subclause of the applicable accreditation standard;
- offer any positive feedback where appropriate.

Assessment report and coding of findings

The NATA Lead Assessor prepares the overall report on the assessment but will seek assistance from you as necessary.

Findings raised in the assessment report will be coded as follows:

Code	Explanation
<p>C (Major nonconformity)</p>	<p>May include, but not limited to, the following:</p> <ul style="list-style-type: none"> • An issue that contributes directly, or has the potential to contribute directly, to the reliability of test results (e.g. inadequate staff training, calibration deficiency, inadequate quality control). This is irrespective of whether the issue is random/infrequent or systemic; • An issue, that whilst it does not contribute directly to the reliability of test results, is systemic (i.e. the same deficiency has occurred on at least a number of occasions); • An issue that contributes directly to how results may be interpreted by the client (e.g. sampling deficiencies); • An issue that has been raised previously as a minor nonconformity but has not been fully or appropriately addressed. <p>A response is required on major nonconformities, including the cause analysis, the action taken and supporting evidence.</p>
<p>M (Minor nonconformity)</p>	<p>May include, but not limited to, the following:</p> <ul style="list-style-type: none"> • An issue is random or infrequent (e.g. only a few staff training records have been found to be out of date); • An issue that does not contribute directly to the reliability of test results but is still a criterion for accreditation (e.g. all staff have received appropriate training for an updated method but this has not been recorded). <p>For initial assessments and variation visits, minor nonconformities must be addressed as per major nonconformities.</p> <p>For all other visits, the cause analysis and action taken or planned to be taken is required. Supporting evidence does not need to be submitted as this will be reviewed at the following assessment visit.</p>
<p>Observation</p>	<p>This may be a recommendation, information, clarification, a reminder or flag for follow-up/review at the next assessment.</p> <p>Observations do not require a response.</p>

Closing meeting

Following the final team meeting, the assessment team and relevant facility staff gather for the Closing Meeting.

A copy of the interim report prepared by the NATA Lead Assessor is made available to the facility.

The NATA Lead Assessor will direct the meeting and present a summary of the findings of the assessment to the facility and allow discussion. The NATA Lead Assessor may also invite the Technical Assessor(s) to raise any comments as agreed during the final team meeting.

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

- reconfirming the purpose of the assessment and the scope of accreditation;
- presenting the assessment findings, including the coding of these;
- inviting the facility staff to comment on any of the findings and resolving any concerns or differences of viewpoints expressed;
- confirming the response date for any nonconformities identified;
- describing the next steps in the process before the accreditation status is confirmed by NATA;
- thanking the facility for its cooperation during the assessment.

10. Post assessment

Cause analysis and corrective action

The facility will be required to respond by the due date to any nonconformity raised in the assessment report.

Addressing a nonconformity involves:

- analysing the extent of the cause (e.g. root cause analysis);
- identifying the impact on work already performed (e.g. have any reported results been compromised?);
- taking specific action to rectify the cause(s), which may include updating existing processes and addressing the impact on any work already performed;
- continuing to monitor the action taken to ensure that it is effective.

The NATA Lead Assessor is responsible for reviewing the facility's response. However, they may seek advice from the Technical Assessor involved in the assessment, notably for nonconformities of a technical nature.

Further information on cause analysis and corrective action is provided in Annex C

11. Assessment techniques

Under the direction of the NATA Lead Assessor, the assessment team must work together in an objective, effective and efficient manner in accordance with the assessment timetable.

The role of the assessment team is to gather information (evidence) and determine whether a facility satisfies (or not) the NATA Accreditation Criteria.

There are different means of gathering information including:

- asking questions;
- listening;
- observing activities;
- reviewing documentation.

Questioning techniques

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

Open questions

These questions help:

- elicit answers of substance;
- keep the dialogue flowing.

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

Who ?

What ?

When ?

How ?

Where ?

Why ?

Direct or closed questions

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

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

Here are some examples:

“Are you the person who normally performs this test?”

“Do you know who does....?”

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

Hypothetical questions

These questions may be helpful because they:

- pose the unusual;
- establish the understanding of a process;
- allow the review of activities that may not be witnessed during the assessment.

Here are some examples:

“What would you do if?”

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

Clarifying questions

These questions help to:

- prevent misunderstandings;
- obtain more detail.

Here is an example:

“Can you please explain as I don’t quite understand what you mean....?”

Talk through the topic

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

- avoid asking the obvious;
- provide reassurance that you are understanding;
- avoid unnecessary periods of silence;
- build a bridge for further questions.

Here is an example:

“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;
- examining records.

Periodically summarise

This is a useful technique because it:

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

Here is an example:

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

Vary your pattern

This can be achieved by:

- using the “show and tell” technique;
- filling-in any gaps in information by asking additional questions;
- using a combination of open questions, direct questions, and hypothetical questions and clarifying questions.

The “*Show and Tell*” technique combines both observing and listening:

- gathers more information;
- tends to be non-threatening;
- requires thorough preparation.

Allow some periods of silence during question time which can:

- give the other person time to think;
- commit the other person to respond.

Questions to avoid

Self-answering questions

Should be avoided because they:

- lead to the expected answer;
- place unnecessary pressure on the other person.

Here is an example:

“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 the following example:

Assessor: *“Do you rotate stock annually?”*

Facility staff: *“Yes”*

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

Ambiguous questions

It is important to phrase questions carefully and clearly to avoid confusion.

Avoid asking, for example:

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

Compound questions

These types of questions should be avoided as they:

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

Avoid asking, for example:

“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

These types of questions should be avoided as they:

- waste time;
- create diversions.

Avoid asking, for example:

“How much did the new computer system cost?”

Questions directed to the wrong person

These types of questions should be avoided as they:

- waste time;
- can generate both confusion and tension.

Listening

If we do not listen attentively, we will miss out on information being provided during discussions and specifically to the questions we are asking.

We are not listening when we are:

- waiting to say something ourselves;
- thinking of our response to the answer while the other person is still speaking;
- jumping to conclusions or making assumptions;
- thinking about something else;
- switched-off.

Poor listening can result in:

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

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 rather than being defensive;
- accept the person despite having a different opinion.

To show we are listening:

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

Observing activities

In addition to asking questions, observing personnel perform their routine activities will provide valuable information.

Observing activities will help you to, for example:

- confirm whether documented procedures are being followed (i.e. staff put into practice what is written and what they have said they should do);
- confirm whether staff demonstrate the competencies required to perform tasks;
- evaluate the effectiveness of supervision provided;
- evaluate the resources available;
- evaluate the appropriateness of the environmental conditions;
- review the availability of equipment and its fitness for purpose;
- etc.

As the assessment process is a sampling exercise, it is not possible nor required that every activity covered by the scope of accreditation be reviewed. Apart from observing activities, it is also possible to have hypothetical discussions concerning activities, or parts thereof, not being observed. It may also be acceptable to observe just key phases of specific activities if the overall process is too lengthy.

As part of the preparation for the assessment, the NATA Lead Assessor will prepare an assessment sampling plan of the activities to be reviewed which are covered by the scope of accreditation. This plan will be discussed and confirmed with you. You should advise the NATA Lead Assessor of any activities you specifically wish to observe being performed so that it is included in the plan. This is especially critical for any activity which will require the facility to prepare in advance.

Reviewing documentation

The type of documents you may review during the assessment include:

- policies and procedures;
- records, including for example:
 - relating to personnel (e.g. training, authorisations, etc);
 - completed forms, worksheets, etc;
 - customer requests for tests;
 - equipment maintenance logs, calibrations, etc;
 - test reports;
 - corrective action reports;
 - etc.

Using your quiet time effectively

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

- collect your thoughts and determine what further evidence you may need to collect;
- write your notes and evidence on the form provided to you;
- touch base with the NATA Lead Assessor or other co-assessors if they are free.

Dealing with tension

An assessment is a stressful experience for staff at every level in the organisation and hence it is not unexpected that tension may exist. Being mindful of this and modifying your behaviours will make for a better experience for both the staff and the assessment team.

Tension during an assessment can lead to:

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

To reduce tension during an assessment:

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

Maintain a professional approach by:

- ensuring your preparation is thorough and complete and your appearance is appropriate and professional;
- staying on track during the assessment by:
 - avoiding diversions, however interesting;
 - following your plan (as far as possible);
 - managing your time;
 - keeping control of your part of the assessment.

To project the right image, ensure you:

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

When things seem wrong:

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

Teamwork

During an assessment, teamwork involves a common purpose and mutual understanding of roles between the Technical Assessor(s) and the NATA Lead Assessor.

To work as a team:

- support one another;
- do not interrupt one another;
- do not undermine anyone in the team;
- respect each other's approach.

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

- everyone to collect their thoughts;
- clarify questions;
- seek each other's advice and support.

If you disagree with a comment or suggestion made by another team member, be sure you:

- ascertain whether or not the issue is important enough to be raised;
- consult with the NATA Lead Assessor if necessary;
- remain professional and never have an open disagreement in front of the facility staff.

Keep the assessment flowing by:

- following a natural sequence of activities;
- avoid back-tracking unnecessarily;
- maintaining an orderly flow of questions;
- avoiding long unnecessary periods of silence;
- projecting confidence.

12. Contacting NATA

NATA may be contacted on 1800 621 666 (free call) or corpcomm@nata.com.au.

Amendment table

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

Section	Amendment
Section 2	Inclusion of new single international accreditation organisation, Global Accreditation Cooperation Incorporated.
Section 9 Conducting assessments	New section on 'opportunities for improvement vs consultation'

Annex A: Common deficiencies

Forward

This Annex includes a summary of common deficiencies noted during assessments. The summary only serves as examples and does not remove the need to perform an appropriate assessment of a Conformity Assessment Body's (CAB) compliance with all relevant clauses of the applicable accreditation Standard.

Personnel procedures and records

Deficiency examples:

- lack of records related to training, authorisation of personnel to perform specific activities, and monitoring of competence;
- no procedure for determining (ongoing) competence requirements;
- supervision requirements/technical oversight not met.

CABs are required to have procedures for various activities related to the competence, training, and monitoring of personnel, as well as for retaining records of those activities. There is a list of specific topics that need to be addressed. All relevant personnel must adhere to these procedures, and records of implementation must be maintained in all cases as objective evidence the procedures are being followed.

The ISO conformity assessment Standards state that several elements of competencies must be documented, including education, training, and experience. Each position category that has an influence on the conformity assessment activity results must have a documented level of competency. Additionally, it is important to keep in mind that the CAB must maintain a procedure for determining competence requirements.

Equipment

Deficiency examples:

- no evidence of verification that equipment conforms with specified requirements before being placed or returned into service;
- inadequate metrological traceability or records;
- critical equipment has not been calibrated or has not been included in the CAB's calibration program;
- calibration status of equipment is unable to be identified;
- correction factors or reference values have not been updated and/or applied;
- failure to maintain a maintenance plan and/or maintenance records;
- necessary equipment required for the correct performance of the conformity assessment activity was not available;
- no justification for extension of calibration intervals or for expired reagents or standards in use.

The term "equipment" is used to refer to all types of conformity assessment activity resources, including measuring equipment, reference standards, reference

materials, reagents, consumables, and more. This section requires procedures for all equipment, including, but not limited to, accessibility, maintenance, storage, calibration, and record keeping. It lists the specific equipment records that CABs must maintain for all the equipment which can influence its activities.

When the CAB sends equipment out for calibration, it is imperative for it to be aware of the specific calibration requirements (procedures, frequency ranges, etc.) outlined in a given method.

Externally provided products and services

Deficiency examples:

- no records available to show that actions were taken to ensure that the received services and/or supplies complied with specified requirements or were deemed fit-for-purpose;
- the CAB utilised a supplier that they had not evaluated;
- CAB defined its requirements for evaluating a supplier but failed to include how the supplier will be re-evaluated.

It is impossible to completely control what goes on outside the CAB, but the selection of externally provided products and services is still within a CAB's control. This section requires that CABs determine the suitability of externally provided products and services in a way that supports compliance. It requires that the CAB maintain a procedure and retain records for, defining, reviewing, and approving the CAB's requirements for externally provided products and services, including evaluation criteria.

Method validation and verification

Deficiency examples:

- improper or incomplete estimates of Measurement Uncertainty (MU);
- modification to methods have not been verified;
- lack of validation (e.g. in-house (laboratory-designed/developed) methods, modified standard methods, in-house IVDs).

This clause in the Standards includes multiple points, all of which cover the selection, verification, and validation of methods. CABs not only have to select methods appropriate for their customer's needs but must also have the appropriate documentation and records to show verification and/or validation of those methods.

Additionally, CABs must verify that they are capable of performing a validated method before introducing it. Furthermore, when a validated method is revised, verification must be repeated. The depth of this verification is to be determined by the CAB. However, records must be maintained.

Technical records

Deficiency examples:

- records were discovered with information made illegible or blacked out and/or alterations to records were not signed or initialled and dated;
- insufficient data recorded to establish an audit trail;

- original observations, data and calculations no longer available/retained;
- failure to record all relevant test observations (e.g. environmental conditions such as temperature and humidity, or simply omitting data on when the test was performed and who performed it).

The focus of the section on *Technical Records* is the traceability and reproducibility of results. All CAB activities must have technical records that are detailed enough to reproduce the exact process that initially produced them. This means that many factors will need to be consistently and diligently recorded, and that both original records and their amendments must be retained.

Ensuring the validity of results

Deficiency examples:

- QC data not recorded in a way that trends are detectable;
- participation in Proficiency Testing (PT) or Inter-Laboratory Comparisons (ILC) found to be inadequate;
- PT outliers or QC data was found to be outside of pre-defined criteria and no action was taken to correct the problem;
- no investigation conducted on consistent upward/downward trends of QC data.

CABs must document procedures intended to continuously monitor the validity of test results. CABs must also participate in PT and/or ILC in order to compare their actual performance against that of other CABs. For some CABs, specific elements of these requirements will not be applicable, but the CAB should be prepared to account for why that is the case.

Regardless of the monitoring activities chosen by the CAB, it is important that pre-defined criteria are determined, and that results are recorded in a way to easily detect and evaluate trends.

Reporting of results

Deficiency examples:

- data that was supplied by the customer, results reported outside the scope of accreditation, or those results carried out by external providers not clearly identified;
- no documented decision rule for statements of conformity;
- lack of unique identification that all its components are recognised as a portion of a complete report and a clear identification at the end;
- no identification of additions to, deviations, or exclusions from the method;
- missing date of receipt, date of sampling and/or date(s) of performance of the activity (only applicable where this is critical to the validity and application of the results);
- results not reviewed and authorised prior to release.

There are many variables regarding reports on results, depending on the customer contract, the type of conformity assessment activities performed, and the methods

used. CABs must take an attentive and individualised approach to applying the requirements of this section.

A disclaimer must be made on the report when data provided by the customer can impact the validity of results (e.g. suitability of the sample received and the customer still requires testing to be performed).

Control of records and documents

Deficiency examples:

- an obsolete procedure was witnessed to be in use;
- personnel were witnessed using their own written notes on how to conduct the conformity assessment activity;
- documents were not uniquely identified;
- documents were not reviewed within the required timeframe.

The sections on *Control of Management System Documents* and *Control of Records* focus on retention, currency, availability, unique identification, prevention of unauthorised access and unintended use of obsolete documents or records.

Many CABs' Standard Operating Procedures (SOPs) and other controlled documents are available electronically. The same requirements apply whether hardcopy or electronic versions of documents are used.

Internal audits

Deficiency examples:

- the CAB's internal audit did not verify continued compliance with own requirements for its management system, including the activities carried out under its scope of accreditation;
- unable to provide objective evidence that the internal auditor was trained and qualified to perform the audit;
- the CAB did not retain records of all areas audited;
- the CAB did not follow its own audit program;
- appropriate corrective actions not undertaken in a timely manner depending on the risk of the audit findings.

An internal audit needs to confirm that a CAB's management system and activities are in compliance with the relevant conformity assessment Standard. The language in this section of the relevant Standard is broad to allow CABs to determine the frequency and depth of the audits, depending on the CAB's needs and risk tolerance. Once the internal audit plan is decided, records of implementation are required.

While the ISO conformity assessment Standards ultimately leave it up to the CAB to determine the frequency and depth of internal audits, it is important that CABs adhere to their own internal procedures and plans. When it comes to internal audits, deficiencies are often cited against the CAB's own procedures rather than those described in the relevant Standard.

Management review

Deficiency examples:

- planned schedule for the management review was not adhered to;
- cited deficiencies in this area include all 15 items required by Clause 8.9.2 a) through to o);
- decisions and actions related to the outputs from the management review not recorded.

This clause of the relevant Standard contains a list of items that must be recorded as part of a management review, all of which the CAB must take care to cover and record.

Similar to internal audits discussed above, it is up to the CAB to determine the frequency of their management reviews. However, the intervals shall be planned. It is important for the CAB to follow its own internal procedures here as deficiencies are often cited for not adhering to planned schedules or processes.

Annex B: Method validation and verification

Foreword

The objective of validating a method is to ensure that it achieves its role of reproducible accuracy and is suitable for its intended purposes. All Conformity Assessment Bodies (CABs) are expected to conduct some level of validation whether by verification of the CAB's implementation of published standard methods, or by performing validation studies for new, laboratory-designed/developed (in-house) methods.

Note: 'Method' may also be referred to as 'measurement procedure', 'examination method', 'standard operating procedure', etc. depending on the discipline. This Annex uses the generic term 'method'.

This Annex may be used by Technical Assessors, regardless of the discipline, to ensure relevant aspects in relation to method validation or verification are considered. It does not provide guidance on how these aspects should be considered and evaluated by a CAB. Nor does it address the often-broader scope of validation that considers the project planning, setting of acceptance criteria, implementation, etc. References and additional reading material listed at the end of this Annex provide further guidance on validation and verification protocols but are by no means exhaustive.

For analyses, where a qualitative outcome is reported based on a numerical value, it is expected that method validation or verification is in line with quantitative procedures.

Note: Various terms, e.g. 'calibration', 'measurement', 'testing', 'analysis', 'examination' etc are used to describe conformity assessment activities. This Annex uses 'analysis' in the general sense.

There is no universal agreement on the definition of some of the terms used in method validation and verification. Terminology relating to method validation and verification concepts is diverse and varies between disciplines both in their meaning and the way they are determined. This Annex uses the terminology expressed in the *International vocabulary of metrology - Basic and general concepts and associated terms - 3rd edition (VIM3)* as the VIM3 is a normative document for CABs accredited to, e.g. ISO/IEC 17025 and ISO 15189.

Personnel

Personnel carrying out method development, method modifications, validation or verification studies must be competent in the field of work under study, and/or have sufficient knowledge related to the work to be able to make appropriate decisions from the observations made as the study progresses. The ISO conformity assessment standards, e.g. ISO/IEC 17025 and ISO 15189, are clear that such personnel must be authorised by the CAB to perform such activities.

Records

CABs need to keep records of method validation and verification, including the procedures used for the validation or verification, specification of the requirements, determination of the performance characteristics of the method, the results obtained

and a statement on the validity of the method, detailing its fitness for the intended use.

Note: Commonly used synonyms for method performance characteristics are ‘method performance parameters’, ‘metrological characteristics’, ‘performance properties’ and ‘performance specifications’.

Validation

The VIM3 defines method validation as “**verification**, where the specified requirements are adequate for an intended use”.

CABs are required to validate:

- non-standard methods;
- laboratory-designed/developed methods (in-house methods), including subjective methods (refer to later section);
- standard methods used outside their intended scope;
- amplifications and modifications of standard methods.

Note 1: Validation can include procedures for sampling, handling and transportation of samples, calibration items, etc.

Note 2: Commercially available measuring systems, such as test kits, are becoming increasing common in some disciplines. The CAB is to verify the manufacturer’s published performance data and demonstrate that the method works at the end-user’s premises. Validation must be performed if there are any deviations in the specified use of the commercially available measuring systems including software, or original validated measurement range, third party reagents used on instruments other than intended instruments and where no validation data is available.

The extent (‘scale’, ‘scope’) of validation will depend on the application/circumstance(s) in which the methods will be used and/or the nature of the changes made to a standard method. The CAB has to decide which performance characteristics, noted below, should be investigated in order to validate the method and, in some cases, how detailed the investigation of a single performance characteristic should be.

There must be justification if and where some of the performance characteristics are not deemed relevant, which would typically occur during the planning stage of the validation process. This might, for instance, be omission of the limit of detection if the method is exclusively to be used at high concentrations.

Depending on the application of the method, validation should generally cover but not limited to:

- all applicable matrix types (including variations) (see Note 1);
- all applicable equipment/instruments used by the method;
- working range (measuring interval including linearity);
- ruggedness (robustness);
- selectivity (specificity including interferences);
- sensitivity (inclusivity);

- precision (including repeatability, reproducibility, intermediate precision) (see Note 2);
- accuracy (including stability, recovery, bias or systematic error) (see Note 3);
- limit of detection;
- limit of quantitation;
- evaluation of measurement uncertainty (see Note 4).

Note 1: Validation data should be available for all matrices specified in the scope of the method, and ultimately the CAB's scope of accreditation. If matrix groups or sub-groups are specified, consideration should be given to whether the matrices used for method validation are sufficiently representative to indicate the wider applicability of the method.

Note 2: For qualitative methods, 'precision' cannot be expressed as a standard deviation or relative standard deviation but may be expressed as 'true and false positive (and negative) rates'.

Note 3: 'Bias' is an estimate of a systematic measurement error. The qualitative concept 'trueness' of a method - in this case lack of trueness - is quantitatively expressed as 'bias'.

Note 4: Strictly, measurement uncertainty is not a performance characteristic of the method, but a property of the results obtained using that method.

The method may be validated by one or more of the following processes:

- comparison of results with other validated methods;
- calibration or evaluation of bias and precision using reference standards or reference materials;
- proficiency testing (PT) and inter-laboratory comparisons;

Note: In ISO 15189 the term PT is replaced by EQA (external quality assessment).

- systematic assessment of factors that may influence the result;
- evaluation of method ruggedness by varying controlled parameters, such as incubator temperature, volume dispensed, etc.;
- evaluation of measurement uncertainty of the results based on an understanding of the theoretical principals of the method and practical experience of the performance of the method.

Note: For calibration methods, a systematic assessment of factors that influence the results may be considered a technique for method validation.

Materials which may be used to demonstrate the ability of a method to meet performance specifications include but are not limited to:

- *blanks (calibration blanks, procedural blanks, reagent blanks, solvent blanks, sample blanks, un-inoculated media, etc.):* These allow assessment of how much of the analytical signal is attributable to the analyte and how much is attributable to other causes, e.g. interferences;
- *reference materials (RMs) and certified reference materials (CRMs):* These materials with known properties or quantity values can be used to assess the

accuracy of the method, as well as obtaining information on interferences. Points to consider include:

- are reference materials held for each analyte/determinant?
- are the reference materials certified or verified for purity and identity/speciation?
- where non-CRM reference materials are used, does the CAB have evidence that the RM is fit-for-purpose?
- *fortified (spiked) materials and solutions*: Recovery can be calculated from results of analyses of samples fortified with a reference material;
- *incurred materials*: Incurred materials may be used as a substitute for fortified materials;
- *routine samples, pooled samples*: These can provide information on precision, interferences etc. which could be realistically encountered in day-to-day work. If the analyte content is accurately known, it can also be used to assess bias;
- *synthetic data*: Such data plays a crucial role in various fields such as machine learning, data analysis, and software testing. Artificially generated datasets with known properties can be used to assess how well the method performs under diverse conditions, ensuring its accuracy and ruggedness before applying it to real-world datasets.

Verification

The VIM3 defines method verification as “*the provision of objective evidence that a given item fulfils specified requirements*”.

CABs are required to verify methods that have already been validated, such as:

- standard methods;
- scientifically accepted published methods;
- commercial test methods/kits.

Verification is also required (to the extent necessary) when:

- there is an important change such as a new but similar instrument;
- an instrument software update;
- relocation of equipment;
- when quality control indicates that the performance of an established method is changing with time;
- if the method is revised by the issuing body, etc.

Method verification studies are typically less extensive than those required for method validation. Nevertheless, the CAB is expected to demonstrate, via objective evidence, the ability to achieve the published performance characteristics under their own test conditions.

Points to consider and demonstrate for verification studies include:

- appropriate and justified number of samples used, covering the full range of expected results to be achieved when testing samples, i.e. the verification covers the intended use of the method;
- replicate and repeat analyses (to demonstrate accuracy and precision);

Note: The estimate of measurement uncertainty is an indicator of precision and can be used to verify a CAB can perform the method satisfactorily.

- bias studies (including matrix variation studies);
- limit of detection (if applicable);
- limit of quantitation (if applicable);
- linearity studies (if applicable);
- correlation with existing validated methods or comparisons with known outcomes.

For *multi-site accreditation* where a method has been validated at another accredited site:

- is objective evidence available to demonstrate that the CAB can achieve equivocal and/or comparable performance for application of the method under the test conditions applied at the site(s) where the method is to be adopted?
- in addition to the points raised above, has consideration been given to samples exchanged between sites?

Validation and verification of subjective methods

Validation and verification requirements also apply to subjective methods. Such methods are based on interpretive decisions (e.g. handwriting, firearms and signal processing in a forensic laboratory, microscopic identifications, non-destructive testing methods, etc.).

A subjective method is one where the experience and expertise of the analyst(s) or examiner(s) however named, is a significant determinant on whether or not samples or test items are said to meet certain criteria. The results are based on qualitative data and the individual's expertise in interpreting that information and appropriate application of subsequent processes.

The validation or verification of such methods is centered on the demonstration of the competence of personnel. Validation or verification parameters which should be considered include but not limited to:

- precision (reliability, consistency, including repeatability, reproducibility);
- ruggedness;
- accuracy (incl. sensitivity and selectivity).

The method may be evaluated by one or more but not limited by the following processes:

- collaborative exercises such as PT and inter-laboratory comparisons.

- inter- and/or intra- examiner variability of decision (systematic assessment of how the output of the examiner's findings varies depending on the input i.e., the samples or test items presented for analysis);
- inter- and/or intra-examiner variability of the detection of features and other attributes (systematic assessment of the thought process or methodology of the examiner).

Note: Intra-examiner variability (i.e. within-examiner consistency) defines the stability or repeatability of data recorded by one individual across two or more trials. Inter-examiner variability refers to consistency between different examiners.

Note: The above two bullet points are also referred to as "black box" and "white box" techniques to evaluate decisions made in a variety of forensic disciplines.

References

- 1) Joint Committee for Guides in Metrology (JCGM) – *International vocabulary of metrology - Basic and general concepts and associated terms - 3rd edition (VIM3)*

Further information

Additional sources and literature related to method development and validation is available as a 'Reading list' under the menu item 'Publications' on the Eurachem website at www.eurachem.org including:

- 1) Eurachem Guide '*The Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics*'

Several discipline specific standards and guides on method validation and/or verification have been developed. These include but are not limited to:

Reference Material Producers:

- 1) ISO Guide 35 '*Reference materials - Guidance for characterization and assessment of homogeneity and stability*'

Note: ISO's Technical Committee for Reference Materials, ISO TC 334, is currently developing new Standards that will take the place of the current Guide. This includes ISO 33405 '*Reference materials - Approaches for characterization and assessment of homogeneity and stability*' and ISO 33406 '*Approaches for the production of reference materials with qualitative properties*'.

Microbiology

- 1) ISO 16140 series – '*Standards for validation and verification of microbiology methods*'

Human Pathology:

- 1) National Pathology Accreditation Advisory Council (NPAAC) '*Requirements for quality control, external quality assurance and method evaluation*'
- 2) National Pathology Accreditation Advisory Council (NPAAC) '*Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs)*'
- 3) The Clinical and Laboratory Standards Institute (CLSI) offers a library of method evaluation standards and method verification guidelines that provide concise

explanations and step-by-step instructions for evaluation of test method performance characteristics such as precision and accuracy.

<https://clsi.org/standards/products/method-evaluation/documents/>

- 4) Australian Association for Clinical Biochemistry and Laboratory Medicine (AACB) Guideline *'Recommendations for Verification of Assays Performance -including Point of Care'*

Legal (incl Forensic Science):

- 1) A number of validation guidelines for forensic disciplines are listed on the Scientific Working Group on DNA Analysis Methods (SWGDM) website <https://www.swgdam.org/publications>
- 2) Australia New Zealand Policing Advisory Agency National Institute of Forensic Science (ANZPAA NIFS) *'A guideline to forensic fundamentals - Identifying the underpinning science of human based forensic science disciplines'*
- 3) Organization of Scientific Area Committees (OSAC) for Forensic Science Technical Series 0004 *'Human factors in validation and performance testing of forensic science'*
- 4) European Network of Forensic Science Institutes (ENFSI) *'Guidelines for the single laboratory validation of instrumental and human based methods in Forensic Science'*
- 5) The President's Council of Advisors on Science and Technology (PCAST) *'Report to the President - Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods'*

Annex C: Cause analysis and corrective action

This Annex provides guidance on how to review the cause analysis of a Conformity Assessment Body's (CAB's) submission to a nonconformity.

While the NATA Lead Assessor is responsible for reviewing a CAB's response to nonconformities, on occasion they may seek advice from you, as the Technical Assessor involved in the assessment, notably for nonconformities of a technical nature.

Cause analysis

Cause analysis is an investigation to identify a nonconformity's underlying (core) issue to the extent necessary. This is the issue which may, or may not, have precipitated a series of events which resulted in the nonconformity.

An issue is considered the cause if addressing it prevents, or minimises, the nonconformity from recurring. The cause may be a single deficiency or deviation from a process but in other cases, it may be the culmination of a sequence of failures.

The primary focus of cause analysis is to address the process(es) and not simply the symptom(s) and should consider the chain of precipitating events, or contributing factors, which led to the nonconformity.

There are various approaches to cause analysis, including but not limited to:

- 5 whys;
- fishbone (affinity/fault tree);
- pareto;
- barrier analysis.

A structured approach facilitates the process to investigate a nonconformity. This process should include:

- identifying what happened;
- determining why it occurred;
- what can be, or is done, to prevent recurrence.

ISO/IEC 17011 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies* requires the Accreditation Body (AB) to assess a CAB's cause analysis and its subsequent corrective action.

The analysis must be sufficiently detailed to identify the cause(s) and provide detail(s) of the extent and impact of the nonconformity.

The cause analysis is not a restatement of the nonconformity

When reviewing submissions from the CAB, ask yourself the following question:

Is there a clear and sufficiently detailed relationship between the cause(s) and the nonconformity?

Note: A complete description of every possible cause is not expected. Further, if the cause(s) has been correctly addressed, it should be expected that the nonconformity will not recur or be minimised.

Corrective action

The principles for considering cause analysis also apply to considering corrective action.

Corrective action is described as the steps taken to address the cause(s) of a nonconformity and to mitigate its recurrence.

Where you, the Technical Assessor, have reason(s) for rejecting the cause analysis, it must be justified.

Further, if the cause analysis is accepted, but the CAB has not addressed the cause in the action taken, then asking for information is appropriate.

Nonconformity “creep”

Nonconformity “creep” occurs when review of a CAB’s submission leads to further questions and responses requested (from the CAB) which are not pertinent to the original nonconformity.

Nonconformity “creep” is *not appropriate!*

The following example illustrates “creep”:

During an assessment, a nonconformity was raised that the CAB did not have the right equipment available to conduct an analysis.

To resolve the nonconformity, the CAB submitted a cause analysis along with details of the corrective action taken, which included a purchase order and photographic evidence of the new equipment.

Subsequently, the CAB was asked to provide the calibration certificate for the new equipment.

For this example, the CAB only needed to address the issue of having the right equipment available. The nonconformity did not state that the equipment needed to be calibrated as the accreditation criteria already specify that equipment must be maintained which may include calibration.

The review of cause analysis and action taken must not result in requesting further information when the identified cause(s) directly relate to addressing the nonconformity.

Where the cause analysis has identified significant technical issues that were not uncovered at the assessment, it cannot be ignored. Any points of concern should be discussed with the NATA Lead Assessor, who will determine a course of action.

Annex D: Measurement uncertainty and decision rules for statements of conformity

Foreword

When testing a product, material, or process, Conformity Assessment Bodies (CABs) often need to determine if the results comply with specified requirements, such as regulatory or customer limits. This process (i.e. compliance decision) is guided by two critical concepts: 'decision rules' and 'statements of conformity'.

This Annex provides an overview how measurement uncertainty affects compliance decisions, how decision rules are applied, and how statements of conformity are generated. It also provides guidance on how to assess these during an assessment, where relevant.

ISO/IEC 17025 does not prescribe the decision rule a CAB is to adopt when making a statement of conformity to a specification or standard.

Further guidance on decision rules, if no standard published rules apply, can be found in the literature referenced at the end of this Annex. Where further information is required regarding the implementation of various decision rules, the reader is referred to JCGM 106 *'Evaluation of measurement data - The role of measurement uncertainty in conformity assessment'*.

Definitions

acceptance interval **(acceptance zone)**

interval of permissible measured quantity values

Note: Unless otherwise stated in the specification, the acceptance limits belong to the acceptance interval.

acceptance limit

specified upper or lower boundary of permissible measured quantity values

decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

guard band

interval between a specification limit and a corresponding acceptance limit

rejection interval **(rejection zone)**

interval of non-permissible measured quantity values

simple acceptance

a decision rule in which the acceptance limit is the same as the specification limit, taking into consideration the measurement uncertainty and risk (such as false accept or false reject and statistical assumptions) for the given situation

specification interval

(specification zone; tolerance interval; tolerance zone)

interval of permissible values of a property

specification limit

(tolerance limit)

specified upper or lower boundary of permissible values of a property

Note: Specification limits can be 'single-sided' (e.g. the maximum storage temperature for a water sample for microbiological analysis is 4°C) or 'two-sided', describing a specification interval between upper and lower specification limits (e.g. the laboratory temperature must be maintained between 18°C and 22°C).

Measurement uncertainty

What is measurement uncertainty?

Measurement uncertainty quantifies the range of possible values within which the true value of a measured quantity lies, expressed with a confidence level (typically 95%).

Purpose: Helps assess the reliability of measurement results when determining conformity to specifications. Its application minimises incorrect decisions, such as passing non-conforming products (false accept) or failing acceptable ones (false reject) based on the decision rules adopted and their associated risks.

Example: A laboratory tests the pH of a drinking water sample and measures it as 7.3 ± 0.1 (with 95% confidence). The true value of the pH thus lies between 7.2 to 7.4. This range can be compared to the specified limit (in this case 6.5 to 8.5) to determine whether the water complies or not, which in this case it does.

Decision rules

What is a decision rule?

A decision rule describes how measurement uncertainty is considered ('directly' or 'indirectly') when determining whether a measurement result complies with a specification. The rule establishes the framework for deciding between acceptance, rejection, or inconclusive outcomes.

Purpose: A decision rule helps ensure that:

- measurements are evaluated consistently and transparently;
- the risk of making incorrect decisions (false acceptance or rejection) is managed effectively through guard banding or through controlling the allowable range of uncertainty;
- compliance decisions are aligned with customer and regulatory requirements.

- Note:**
- decision rules should be tailored to balance the risks taking into account the requirements of the customer or regulatory bodies;
 - define acceptance and rejection limits;
 - specify the level of confidence (e.g. 95%) for compliance decisions;
 - document procedures for cases requiring further testing or inconclusive results.

Key components of decision rules:

- acceptance and rejection intervals
 - the boundary between these intervals is determined by the acceptance limit often adjusted by a guard band.
- guard bands
 - a guard band (g) is a buffer zone between the specification limit (SL) and acceptance limit (AL) often based on measurement uncertainty.

Note: A guard band may reduce or increase the acceptance interval to provide higher or lower confidence respectively when making compliance decisions.

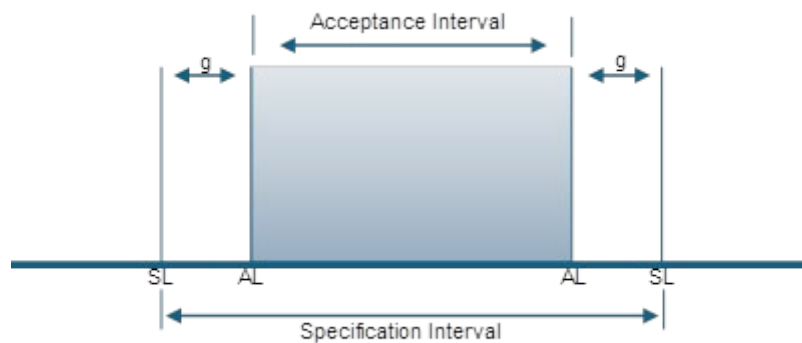


Figure 1. Key components of decision rules.

Types of decision rules:

Three types of common rules are described below:

1) Simple acceptance rules

Include rules where the acceptance criteria equate to the specification interval (i.e. acceptance interval = specification interval).

If the result, taking into account measurement uncertainty, falls within the specification interval then it is considered compliant.

Using the previous example, the pH of a water sample must fall within the range of 6.5 to 8.5 to meet drinking water quality standards. This means a sample with a measured value of 6.6 ± 0.1 passes.

Simple rules are sometimes called “shared risk” rules as the risks in making a conformity decision are equally shared between the CAB or producer and customer (consumer).

- measured values up to and including the specification limits are taken to indicate conformance, with an associated risk of false decision of 50% for values at the specification limit (and potentially higher risk for two-sided specifications);
- to reduce incorrect decisions to levels acceptable to both the CAB and the customer, the measurement uncertainty is taken into account by defining constraints that must be met *before* the simple acceptance can be made. These constraints are chosen to limit the risk associated with the decision.

The role of measurement uncertainty in this type of decision process is to act as a pre-condition for the use of simple acceptance criteria;

- another practical simple acceptance decision rule is referred to as the ‘accuracy method’. In this approach, a well-characterised test method is used, and sources of uncertainty are minimised by use of measuring instruments with maximum permissible errors within specified limits, environmental influences, such as temperature and relative humidity, are maintained within specified limits and having good control of laboratory procedures and staff competency.

By controlling sources of variability within prescribed limits, the measurement uncertainty associated with a best estimate of a measurand is assumed to be negligible, is not explicitly evaluated, and plays no role in an accept/reject decision.

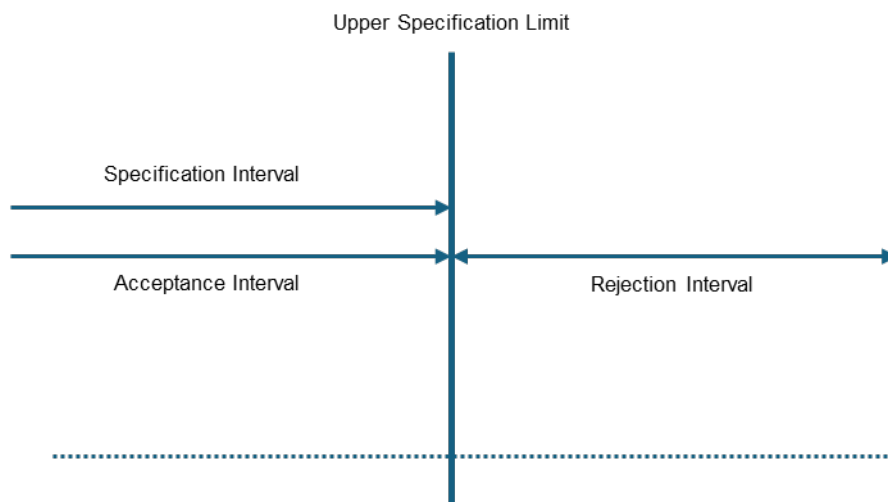


Figure 2. Acceptance and rejection intervals for simple acceptance with an upper limit. The acceptance limit is equal to the specification limit. (Figure adopted from Eurachem/CITAC Guide ‘Use of Uncertainty Information in Compliance Assessment’).

2) Guard banded rules

For measured values close to the specification limit, or when the uncertainty is large, simple acceptance can lead to an unacceptably high risk of an incorrect decision, such as false acceptance or rejection. In such cases, the acceptance

interval can be adjusted by a guard band to reduce the risk of incorrect decisions.

The guard band is an interval between the specification limit and acceptance limit. A result falling within the guard band may be considered a “conditional” pass or fail depending on the specific definition for the rule adopted.

For example, for the same water pH range, applying a guard band of ± 0.2 reduces the acceptance interval to 6.7–8.3, making a pH result of 6.6 ± 0.1 non-compliant.

Note: In order to avoid CABs’ dependency on guard bands, regulators often take measurement uncertainty indirectly into account.

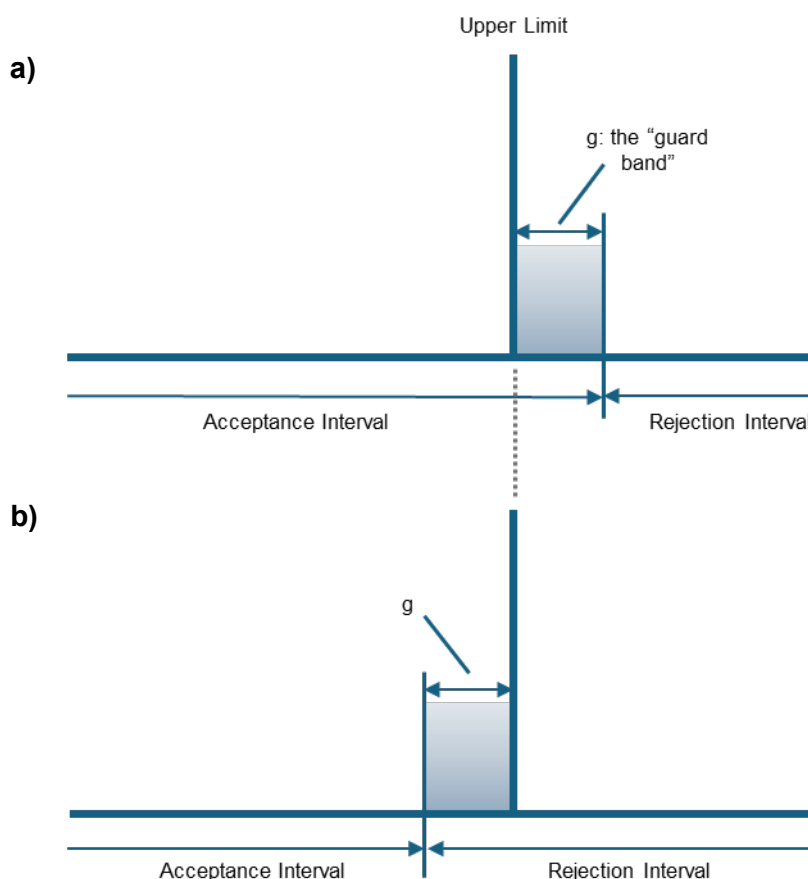


Figure 3. Acceptance and rejection intervals for an upper limit. The figure shows relative positions of the acceptance and rejection intervals for **a)** high confidence of correct rejection; **b)** high confidence of correct acceptance. The upper end of the acceptance interval is the acceptance limit. (Figure adopted from Eurachem/CITAC Guide ‘Use of Uncertainty Information in Compliance Assessment’).

3) Non-binary rules

Introduces additional classifications like "conditional pass" or "conditional fail" or “inconclusive” for results overlapping with the specification limit.

For example, a pH of 6.5 ± 0.1 is classified as "conditional fail" because the range overlaps the lower limit of 6.5.

Statements of conformance

What is a statement of conformity?

A statement of conformity is a declaration that a measurement result meets or does not meet a specified requirement, taking into account the applied decision rule and measurement uncertainty.

Common formats:

- binary statement
 - pass: The result is within the acceptance interval;
 - fail: The result is in the rejection interval;
 - other terms often used include: "in-tolerance/out-of-tolerance"; "in-spec/out-of-spec", "compliant/non-compliant".
- non-binary (conditional) statement
 - highlights uncertainty, e.g. "conditional pass" or "pass with overlap", "conditional fail" or "fail with overlap", indicating results are close to or overlap the limit.

Example statements:

- binary: "The measured pH is 7.3 ± 0.1 . Result: Pass, as it lies within the acceptance interval of 6.6–8.4 (guard banded)";
- non-binary: "The measured pH is 6.5 ± 0.1 . Result: Conditional fail, as the uncertainty overlaps the lower specification limit".

Key components of conformity statements:

- measured value and measurement uncertainty: Includes the result obtained and the range within which the true value of the measurand is expected to lie. For example, pH 7.3 ± 0.1 ;
- specification limit: The predefined upper and/or lower permissible boundaries. For example, pH 6.5–8.5;
- decision rule applied: For example, guard banded with ± 0.2 .

Incorporating measurement uncertainty into conformity statements:

- clear pass/fail: Use decision rules to determine if the measured value, including measurement uncertainty, falls within acceptance limits;
- for example, a result of 98 with a $\pm 2\%$ uncertainty could still meet a 100-limit specification if the guard band allows it.

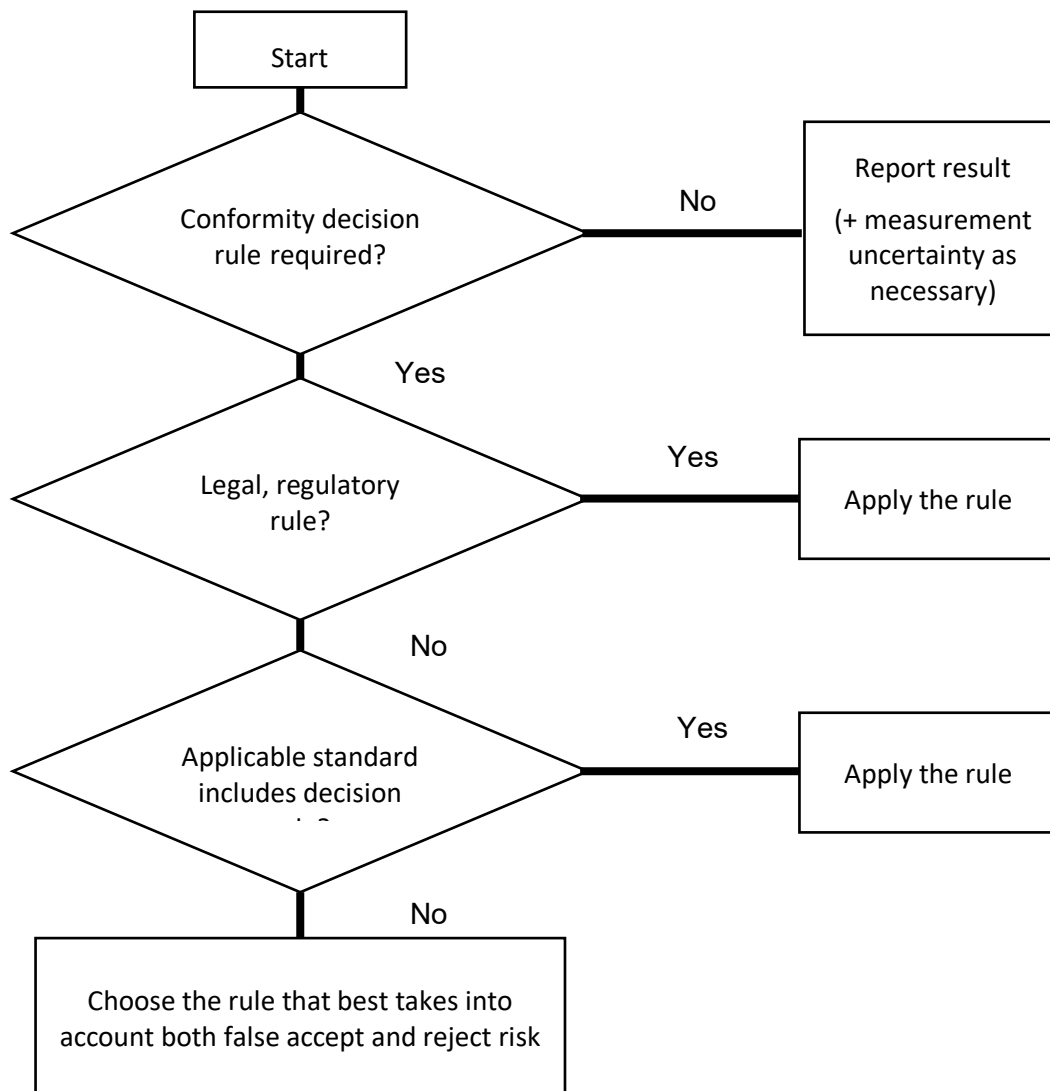
Reporting requirements:

- include the decision rule used (e.g. “simple acceptance” or “guard banding”);
- clearly state the measurement result and associated measurement uncertainty;
- state whether the result is compliant, non-compliant, or inconclusive, based on the decision rule;
- examples:
 - simple compliance statement: "The measured value is 19.5 mg/L \pm 0.5 mg/L. This is within the specified range of 15–20 mg/L. Result: Compliant";
 - conditional compliance statement: "The measured value is 20.2 mg/L \pm 0.3 mg/L. Due to uncertainty, the upper limit is within the uncertainty range. Result: Inconclusive".

Assessing decision rules for statements of conformity (where relevant)

- has the CAB documented its decision rules (ISO/IEC 17025 clause 7.1.3)?
 - has the CAB taken into account the level of risk associated with the chosen decision rule (ISO/IEC 17025 clause 7.8.6.1)?
- Note:** Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.
- verify that decision rules specify:
 - the acceptance and rejection criteria;
 - the level of probability for compliance/non-compliance;
 - how measurement uncertainty is taken into account.
 - unless inherent in the requested specification or standard, is there agreement between the CAB and its customer on decision rules (ISO/IEC 17025 clause 7.1.3)?
 - unless it is inherent in the requested specification or standard, the measurement uncertainty and decision rule are stated in reports (ISO/IEC 17025 clauses 7.8.3.1 and 7.8.4.1)?
 - documentation of CAB personnel includes knowledge, skill and authorisation to apply decision rules and make statements of conformity (ISO/IEC 17025 clause 6.2.6)?

Figure 4. The following figure (adopted from ILAC G8 'Guidelines on Decision Rules and Statements of Conformity') provides general guidance for the selection of decision rules:



References and further information

Additional sources and literature related to Measurement Uncertainty and Decision Rules for Statements of Conformity include but are not limited to:

- 1) ASME, B89.7.3.1 '*Guidelines for Decision Rules: Considering Measurement Uncertainty in Determining Conformance to Specifications*'
- 2) Eurachem/CITAC Guide '*Use of Uncertainty Information in Compliance Assessment*'
- 3) EUROLAB Technical Report No.1 '*Decision rules applied to conformity assessment*'
- 4) ILAC G8 '*Guidelines on Decision Rules and Statements of Conformity*'
- 5) ISO/IEC 17025 '*General requirements for the competence of testing and calibration laboratories*'
- 6) ISO/IEC Guide 98-4 '*Role of measurement uncertainty in conformity assessment*'
- 7) JCGM 100 '*Evaluation of measurement data - Guide to the Expression of Uncertainty in Measurement*' (GUM)
- 8) JCGM 106 '*Evaluation of measurement data - The role of measurement uncertainty in conformity assessment*'
Note: This document is also available as ISO/IEC Guide 98-4
- 9) OIML G19 '*The role of measurement uncertainty in conformity assessment decisions in legal metrology*'
- 10) WADA TD2019DL '*Decision limits for the confirmatory quantification of threshold substances*'