AS 4633 (ISO 15189) APPLICATION DOCUMENT

SUPPLEMENTARY REQUIREMENTS FOR ACCREDITATION IN THE FIELD OF MEDICAL TESTING

2005 Version 1
Contents

SECTION 1     Introduction                       4
SECTION 2     Accreditation Procedures          6
SECTION 3     Supplementary Requirements for Accreditation   10
SECTION 4     Equipment Calibration Intervals        21
SECTION 5     Classes of Test                    26
SECTION 6     Appendices                         29
SECTION 7     References                         32
SECTION 1: INTRODUCTION

SCOPE

The particular requirements for the quality and competence of medical testing laboratories are described in AS 4633: 2004 Medical laboratories - Particular requirements for quality and competence. As this standard, issued by Standards Australia, has been reproduced from, and is identical to, ISO 15189, the two standards will be collectively referred to hereafter as “ISO 15189”. These requirements are designed to apply to all types of pathology testing and therefore often need to be interpreted with respect to the type of testing concerned, and the techniques involved.

This document provides an explanation of the application of ISO 15189 to the various disciplines of pathology testing and also a description of the NATA accreditation procedures applied in this field. Medical Testing laboratories must comply with this document, all relevant clauses of ISO 15189, the NATA Rules, NPAAC standards and relevant statutory requirements for accreditation to be granted and maintained. This document also provides interpretive detail of the NPAAC standards. Additional information relating to specific areas of testing or changes or additions to accreditation requirements or policies may be issued by NATA from time to time in the form of Technical or Policy Circulars. These shall supersede any previous requirements where indicated. This document must therefore be read in conjunction with all of these references which together comprise the NATA Accreditation Requirements (NAR). The contents of the NAR are:

1. About NATA and Accreditation
2. AS 4633: 2004 Medical laboratories - Particular requirements for quality and competence
3. AS 4633: 2004 (ISO 15189) Medical Testing Application Document - Supplementary Requirements for Accreditation in the Field of Medical Testing
4. NATA Rules
5. Current Policy/Technical Circulars (where relevant)

Please note that updates on policy/technical matters are also notified in NATA News and via the NATA website at www.nata.asn.au.

Technical Notes are also available to assist laboratories in relation to particular technical issues. A number of these are referenced in this document. They are intended to provide guidance and therefore do not contain requirements for accreditation, unless specifically indicated in this document. Copies may be obtained from NATA offices or from our website.

A copy of the NATA Accreditation Requirements must be readily available to staff working in a NATA accredited or applicant laboratory.

APPLICATION

The field of Medical Testing is one of several fields of testing into which NATA’s laboratory accreditation program is currently organised. It covers tests on specimens of human origin and includes diagnostic testing in the disciplines of:

- Anatomical Pathology
- Immunohaematology
- Assisted Reproduction Procedures
- Immunology
- Chemical Pathology
- Medical Practice Pathology
- Cytogenetics
- Microbiology
- Haematology
- Molecular Genetics

The field also covers tests on specimens of human origin for other purposes such as those associated with blood transfusion services and clinical trials.

These accreditation criteria are applicable to all Medical Testing laboratories irrespective of size, range of testing or number of personnel. It should however be noted that it is not possible to set rigid requirements for all aspects of a laboratory’s operation. Some flexibility is necessary so that each laboratory’s unique situation can be considered. The acceptability (or otherwise) of certain practices can therefore only be determined by assessment. Information on the assessment process is contained in Section 2.

Application Documents for ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories are available for NATA’s other laboratory accreditation fields, as listed below. Please contact one of our offices or visit our website to obtain copies if these are of interest.

- Acoustics & Vibration Measurement
- Information Tech. Testing
- Biological Testing
- Mechanical Testing
- Chemical Testing
- Medical Imaging
- Construction Materials Testing
- Non-destructive Testing
- Electrical Testing
- Optics and Radiometry
- Forensic Science
- Heat and Temperature
- Measurement
- Phys. & Dm. Metrology
- Veterinary Testing

The accreditation requirements for the new RANZCR/NATA Medical Imaging program are also now available from NATA’s website.

ADMINISTRATION

The Association’s accreditation activities in the field of Medical Testing are administered, under the direction of its Board, by the Medical Testing Accreditation Advisory Committee. The current NATA Rules outline the functions of the Board and the Accreditation Advisory Committee.

NATA/RCPA

The Medical Testing accreditation scheme is run jointly with the Royal College of Pathologists of Australasia (RCPA). The College has representation on the Accreditation Advisory Committee. Assessment reports may be reviewed by the NATA/RCPA Liaison Officer, Deputy NATA/RCPA Liaison Officer and/or Chairman of the Medical Testing Accreditation Advisory Committee under various circumstances.
The Memorandum of Understanding (MOU) between the RCPA and NATA was extensively reviewed before being re-signed in June 2004 for a further four years.

**National Pathology Accreditation Advisory Council (NPAAC)**

NPAAC, established in 1979, is a body chaired by an appointee of the Commonwealth Department of Health and Ageing. It has nominees from all states and territories and professional bodies such as the RCPA, AMA, AIMS, AACB, HSA and ASM. Its task is the development of standards for the accreditation of pathology laboratories.

The NATA/RCPA accreditation scheme assesses laboratories to the accreditation materials developed by NPAAC and these are referenced throughout this booklet. Laboratories are expected to hold current editions of the relevant Standards and Guidelines issued by NPAAC. These documents are available from the NPAAC website (www.health.gov.au/npaac).

Commonwealth Accreditation

NATA has a formal agreement to assess laboratories for the Health Insurance Commission (HIC). This agreement is detailed in the Deed for inspection of premises for the purpose of sub-section 23DN(i) of the Health Insurance Act 1973 and is applicable only for Australian laboratories. All further references to procedures for HIC purposes apply to Australian laboratories only.

The HIC requires that a report from NATA be submitted by every laboratory with their application or renewal form for an Approved Pathology Laboratory. Usually, the Report on Laboratory Premises is issued by NATA after advisory visits and assessments.

**TERMINOLOGY AND PRESENTATION**

The clause numbers in bold in Section 3 follow those of ISO 15189 but as not all clauses require interpretation the numbering may not be continuous. It is recognised that not all testing activities are performed in a “laboratory”. The term “laboratory” is, however, used throughout this document.

The words “shall” and “must” are used interchangeably throughout this document and describe mandatory criteria for accreditation. The word “should” is used where guidance is provided but does not preclude other acceptable practices. Where a smaller size font has been used this indicates matters of an advisory or informative nature.

Any references to the NATA Rules, Fee Schedule, Technical Notes, NPAAC documents etc imply the current version of such documents.

Where the words “policy” and “procedure” are used in ISO 15189 it is possible that one document may meet the requirements of the standard. This will be determined at assessment.

References to “him” also imply “her” where this is the case.

**LEGISLATION**

It is the responsibility of each laboratory to ensure that it complies with all relevant legislation. Legislative requirements take precedence over, or provide additional criteria to, those detailed in this document. It is strongly recommended that laboratories hold copies of relevant legislation.
SECTION 2:
ACCREDITATION PROCEDURES

The following information is provided to assist laboratories seeking accreditation or extensions to accreditation in the field of Medical Testing. General information is also provided with regard to NATA’s policies and procedures.

It should be noted that there are some differences between the fields in regard to the order in which these steps are followed. Where accreditation may be required in a number of different fields, every attempt is made to harmonise and coordinate accreditation activities. Corporate accreditation is available in defined circumstances to assist this process. A Policy Circular is available explaining this process and can be obtained from our offices or on our website.

There may also be a need to vary the steps detailed below in the case of applications from overseas laboratories. Once again, every attempt is made to ensure the accreditation process is carried out in the most efficient and effective way for all parties concerned.

Where applications or accreditations are required that include non-laboratory NATA accreditation activities (such as the Reference Material Producers Accreditation Program, Proficiency Testing Scheme Providers Accreditation, GLP Recognition Program or Inspection Accreditation) every effort is also made to appropriately coordinate activities.

The transition period for compliance with ISO 9001: 2000 ended on 1 January 2004. All facilities holding quality management system certification are now required to comply fully with this Standard. ISO 9001:2000 differs from the previous versions in that the emphasis is more outcome based and there are fewer requirements for documented procedures and records.

Compliance with ISO 9001: 2000 may not therefore translate to compliance with the management system elements of ISO 15189 as the standard was prepared during the revision of ISO 9000. In conducting assessments, NATA cannot therefore take into consideration a laboratory’s ISO 9001 certification.

Fees for Services

The various parts of the process where charges are levied are indicated. Specific information on charges can be obtained from our current Fee Schedule, from NATA staff or by consulting our website.

PRELIMINARY STEPS

The laboratory is encouraged to hold discussions with relevant NATA technical staff before lodging a formal application for accreditation.

When seeking accreditation, laboratory staff should also familiarise themselves with the NATA Accreditation Requirements (NAR) for Medical Testing. The NAR can be obtained following discussion with field technical staff and will attract a fee to cover the cost of the accreditation requirements package and postage.

APPLICATION FOR ACCREDITATION

Applications for accreditation may be made only by legally identifiable organisations and only by way of the prescribed application form. The application form can be obtained from any NATA office or the NATA website. An application must be accompanied by the current application fee.

For laboratories seeking HIC accreditation, an advisory visit will need to be conducted prior to lodging an application for accreditation. Laboratories should contact NATA to discuss the necessary arrangements.

On receipt of the application, a questionnaire will be forwarded for completion and return.

ADVISORY VISIT

A pre-application (or advisory) visit will be undertaken of laboratories linked to the HIC’s accreditation for the payment of Medicare benefits. These visits are to be conducted before a laboratory starts specimen testing or processing.

Such a visit is optional, although strongly recommended, for overseas and other non-Medicare linked laboratories.

During an advisory visit, the NATA lead assessor will seek preliminary information and outline the process, requirements and timing of the assessment for accreditation. Please note that a fee will be levied for this service.

Prior to an advisory visit being conducted the laboratory may be asked to provide a copy of its quality manual and associated documentation for review. NATA technical staff will advise exactly what information is required for this review. This activity is known as “document review” and is described below.

DOCUMENT REVIEW

Document review is most often carried out by the NATA staff officer who will be involved in the assessment of the laboratory.

The document review provides a comparison of the laboratory’s documentation and procedures with the accreditation requirements as detailed in the NAR. The NATA lead assessor also makes note of particular references within the laboratory’s documented system that require review at the assessment or areas that appear to require further explanation or investigation. Written feedback will be given. Depending on the extent of the action required, the laboratory may be asked to provide further information prior to the assessment or this information will be sought at the assessment.

A fee may be levied for the document review.

THE ROLE OF THE AUTHORISED REPRESENTATIVE

The authorised representative is the person nominated by the laboratory to be its representative in all matters relating to the application or accreditation. He is the laboratory’s recognised official contact with NATA. Nomination is made in the appropriate place on the application form or when changes are required thereafter, on the Nomination of New Authorised Representative form available for this purpose from any NATA office or the NATA website.
The rights and legal obligations of the authorised representative are detailed in the NATA Rules and Policy Circular No. 14. At a practical level, the authorised representative is normally a senior staff member who is in a position to make decisions regarding the laboratory’s accreditation and to effectively communicate with laboratory colleagues. The authorised representative may also choose to direct NATA to other laboratory staff with whom relevant issues may be discussed.

The authorised representative is required to notify NATA within 14 days if:

- the name or ownership of the laboratory changes;
- changes in duties or departures of key staff occur; or
- significant changes occur to the functions or accommodation of the laboratory.

**ASSESSMENT**

Compliance of an applicant with accreditation requirements is determined primarily by an on-site assessment of its resources, procedures and documentation.

The objective of an assessment is to establish whether the laboratory can competently perform the tests or measurements for which accreditation has been sought. The NATA assessment team is required to investigate the operation of the laboratory against the criteria detailed in the NATA Accreditation Requirements (NARs) for this field (the documents comprising the NAR have been listed above). The assessment team reports its findings to both the laboratory seeking accreditation and representatives of the Medical Testing Accreditation Advisory Committee (AAC). The role and responsibilities of AACs are detailed in the NATA Rules.

The assessment team comprises at least one NATA lead assessor and one or more specialist volunteer technical assessors. The principles for participation of pathologist assessors are detailed in the NATA/RCPA MOU. The NATA lead assessor also reviews the quality system. The size of the assessment team is dependent upon the areas that must be covered in the course of the assessment.

Assessments will generally take at least one working day and may extend over a number of days depending on the range of activities to be covered. Technical assessors are chosen according to their specialist knowledge and are matched as closely to the activities of the laboratory as is possible. Consideration is given to possible concerns about conflicts of interest in selecting assessors.

Laboratory staff will be called upon to discuss, with the technical assessors, technical issues relating to measurements and tests that are in progress, or are carried out by the laboratory. Occasionally, such discussion may be hypothetical. NATA may also request prior to the assessment, or in the course of the assessment that particular measurements or tests be demonstrated. Laboratories undergoing an assessment should expect all areas for which accreditation is sought to be covered in some way.

An exit interview or meeting is normally held at the conclusion of the assessment at which the assessment findings are presented by the NATA lead assessor (on occasion a decision may be made not to undertake an exit discussion due to extraordinary circumstances). It is the prerogative of the laboratory to decide which of their staff should attend this meeting. Generally, the authorised representative would be expected to attend as well as relevant senior staff.

The purpose of the exit meeting is to allow frank and open discussion about the findings of the assessment. Laboratories are strongly encouraged to clarify issues they consider may have been misunderstood by the assessment team and to seek clarification about assessment findings where this may be necessary.

The findings of the assessment team are subsequently confirmed in a written report which has been reviewed by the assessors and, in some cases, members of the Medical Testing AAC. Where necessary the report will detail the action required by the laboratory to allow accreditation to be recommended. In these cases the laboratory will be asked to provide NATA with the necessary evidence that action has been taken as claimed. Occasionally a further visit by a NATA lead assessor or another assessment will be carried out. There are a number of reasons for this, including concerns about the competence of the facility, the inability to assess certain aspects of the facility during the scheduled visit because of lack of availability of key staff, or to review the effective implementation of the corrective action taken as a result of the assessment. The same procedures for assessment will be followed but may concentrate on those area(s) found to be deficient. Charges will be levied for such visits.

**GRANTING ACCREDITATION**

NATA’s Chief Executive grants accreditation following a recommendation by members of the Medical Testing AAC. This recommendation is made when the laboratory has met all the requirements for accreditation. The authorised representative is formally advised of the granting of the accreditation and issued with a certificate of accreditation and the scope of accreditation.

**SCOPE OF ACCREDITATION**

Accreditation is described by classes and sub-classes of test. The collective expression or scope of a laboratory’s accreditation is known as its “scope of accreditation”. These classes and sub-classes are fixed descriptors, free text being used to restrict or amplify the scope as necessary. Where the scope of testing of a laboratory cannot be adequately described by existing descriptors, the Medical Testing Accreditation Advisory Committee may from time to time establish new classes and/or sub-classes of test. A copy of the classes of test available in the field of Medical Testing is provided in Section 5 of this document. Classes of test are however revised from time to time so for the current version please contact a NATA office or visit our website.

Applications for accreditation may be made for one or more classes or sub-classes of test, or for one or more items or specific calibrations or tests within a class of test.

The scopes of accreditation for all NATA accredited laboratories are available on the NATA website at www.nata.asn.au.

**VARIATIONS TO SCOPE OF ACCREDITATION**

Accredited laboratories may request variations to their scope of accreditation. Significant variations will require an assessment. NATA technical staff will provide direction on the information required, the process that will be followed and the fees that will be levied.
AFTER ACCREDITATION

NATA accredited laboratories must continue to comply with all accreditation requirements detailed in the NATA Accreditation Requirements. In order to ensure continued compliance with these requirements, the first reassessment is undertaken after two years. Reassessments are then generally carried out every three years. Shorter reassessment intervals may also be specified. The reassessment follows the same processes and has the same broad objectives as the initial assessment. Laboratories must respond to assessment findings by the nominated response date, otherwise the status of their accreditation will be reviewed.

Reassessments are also undertaken after substantial changes to the staff, other resources or procedures, when a change to the scope of the accreditation is sought, or to ascertain the validity of concerns about a laboratory’s activities. Such concerns may be the result of a complaint, or poor performance in a quality assurance program (QAP). The Board has the right to direct that a reassessment be conducted, with or without notice, at any time.

NON-COMPLIANCE WITH ACCREDITATION REQUIREMENTS

In accordance with the NATA Rules, non-compliance with the accreditation requirements may lead to the accreditation status of a laboratory being suspended or cancelled.

In these circumstances the HIC will be advised and the laboratory will not be able to issue endorsed reports or claim to be accredited for those services affected by the change in status. The NATA Rules define the reasons, processes and the appeals mechanisms that will be followed.

PROVISION OF INFORMATION ON SCOPE OF ACCREDITATION

Details of a laboratory’s scope of accreditation are posted on the NATA website once accreditation has been granted and are also made available to enquirers. The website also lists the date of the last activity and the end date of the approval period.

CONFIDENTIALITY

All information provided by a laboratory in connection with an enquiry or an application for accreditation, and all information obtained in connection with an assessment, is treated as confidential by NATA staff, technical assessors, committee and Board members. All such personnel are made aware of this requirement and have signed confidentiality agreements.

PRIVACY

NATA respects and upholds the rights of individuals to privacy protection under the National Privacy Principles contained in the Privacy Amendment (Private Sector) Act 2000. 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 or are privy to.

The following is a summary of the personal information collected from individuals in applicant and accredited facilities and the disclosure of that information.

Authorised Representative

The authorised representative is an accredited facility’s official contact with NATA. The personal information collected will include: name; position; business address, business telephone, mobile phone and fax numbers; e-mail address. Credit card details may also be held for those purchasing NATA services. This information may be used to:

- administer and manage your accreditation;
- seek feedback from you on ways to improve NATA’s services; and
- provide you information on NATA’s activities and services.

The information may also be made available to enquirers requiring the services of NATA accredited facilities.

Personal information may be disclosed to organisations outside NATA. Such organisations may include:

- 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;
- accreditation bodies with which NATA has a Mutual Recognition Arrangement (MRA);
- professional advisers including accountants, auditors and lawyers;
- credit providers; and
- outsourced service providers managing NATA services.

Laboratory Contact

Recognising that the authorised representative is not necessarily the most appropriate person to answer day to day and technical queries regarding an accredited facility’s activities, NATA provides the opportunity to nominate a person to deal with technical and other enquiries. (This person can, however, also be the authorised representative.)

The personal information collected will include: name; position; business address, business telephone, mobile phone and fax numbers; e-mail address. This information may be given to enquirers and is included in the on-line directory.

Laboratory Personnel

The personal information collected on personnel of the applicant or accredited facility may include: name, position, professional, technical or other relevant qualifications, membership of professional associations and employment history.

This information is used for the conduct of the assessment, reporting on the assessment and the process of granting/continuing accreditation. It may be disclosed to NATA staff members, assessors, assessment observers and NATA committee members, all of whom have signed confidentiality agreements. It may also be disclosed to agencies to which NATA has a legal obligation or with which NATA has a formal agreement.

Disclosure of Personal Information by Applicant and Accredited Facilities at Assessments

In order for NATA to determine compliance with some accreditation criteria, it will be necessary to sight personal information at assessments. Examples might include personal information held
in training records, complaints records, lists of approved suppliers etc. It is the responsibility of the facility to ensure that, in accordance with National Privacy Principle 1.3(d)], it has appropriate arrangements in place to advise individuals that personal information collected may be disclosed to NATA.

**Consent to Disclose Assessment Findings**

Under the agreement with the HIC, NATA must seek consent from laboratories to disclose information to this body. Consent is also sought to disclose information to the RCPA and Department of Human Services (Victorian laboratories only). The Authorised Representative will be asked to sign a form consenting to this disclosure as part of the application process.
SECTION 3: SUPPLEMENTARY REQUIREMENTS FOR ACCREDITATION

4. MANAGEMENT REQUIREMENTS

The following documents may contain specific accreditation criteria or ancillary accreditation information:

- Health Insurance (Accredited Pathology Laboratories - Approval) Principles
- NPAAC Guidelines for Approved Pathology Collection Centres
- NPAAC Guidelines for Cytogenetics Laboratories
- NPAAC Guidelines for Data Communication
- NPAAC Guidelines for Laboratory Procedures Related to the Processing, Storage and Infusion of Cells for Transplantation or Cell Therapy
- NPAAC Guidelines for Quality Systems in Medical Laboratories
- NPAAC Guidelines for Retention of Laboratory Records and Diagnostic Material
- NPAAC Guidelines for the Facilities and Operation of Hospital and Forensic Mortuaries
- NPAAC Guidelines for the Performance of Pathology Surgical Cut-up
- NPAAC Guidelines for the Use of Fluid Based Collection Systems and Automated and Semi-automated Screening Devices in the Practice of Gynaecological (Cervical) Cytology
- NPAAC Information on the Transport of Pathology Specimens
- NPAAC Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques
- NPAAC Requirements for Gynaecological (Cervical) Cytology
- NPAAC Requirements for Supervision of Pathology Laboratories
- NPAAC Requirements for the Validation of In-house In Vitro Diagnostic Devices (IVDs)
- NPAAC Performance Measures for Australian Laboratories Reporting Cervical Cytology
- NPAAC Preparation of Manuals for Administrative Instructions and Personnel Procedures for Laboratories
- NPAAC Standards for Pathology Laboratories
- NPAAC Standards for Pathology Laboratory Participation in External Proficiency Testing Programs
- Australian and New Zealand Society of Blood Transfusion Inc., Guidelines for Pretransfusion Testing, 4th Edition. Laboratories are advised that the application of this document is under review. Whilst acknowledging the statement on p (i) of the Guidelines, that the “recommendations in the Guidelines for Pretransfusion Testing are primarily educative”, the document also states that they “shall be used in conjunction with the requirements of national accreditation authorities, the national blood services and other regulatory bodies”. The matter has been referred to the National Pathology Accreditation Advisory Council for further advice. In the meantime, the guidelines remain a most comprehensive document used by medical and scientific personnel in the area of transfusion testing. It is the intention of NATA/RCPA to ensure that this critical area of testing is performed at the highest possible standard. Thus clauses which state “shall” will continue to be applied as requirements at assessment, until further opinion is provided.

4.1 ORGANISATION AND MANAGEMENT

Staff numbers and supervision

Specific requirements for supervision are described in the NPAAC document Requirements for Supervision of Pathology Laboratories. Laboratories seeking approval from the HIC must comply with the requirements for the relevant NPAAC category. The supervising pathologists and scientists of a Category B laboratory must maintain a record of attendance. Sufficient detail should be included to identify the activities undertaken at the visit. Records must be maintained of professional development or supervised training undertaken. Such records must be available for review at the assessment of the Category B laboratory.

4.2 QUALITY MANAGEMENT SYSTEM

A quality system should provide laboratory management with continuing confidence that results and conclusions are accurate and reliable.

The success of the quality system depends on the commitment of management and the active participation of each member of the laboratory staff. To ensure that everyone fully understands what the expectations are, all elements of the quality system must be clearly articulated in the quality manual and related documentation.
Quality documentation must include or reference the laboratory’s scope of accreditation and policy on the use of the NATA/RCPA endorsement.

### 4.5 Examination by Referral Laboratories

See also 5.8.12 concerning transcription of results.

A competent referral laboratory is defined as a laboratory accredited by NATA or one of NATA’s mutual recognition partners for the tests, measurements or calibrations.

This applies in those cases where a laboratory is required to refer part of its normal service (e.g., due to temporary incapacity, excess workload) or where a laboratory refers due to the need for further expertise and then incorporates the results of the referred test into their own test report for the purpose of formulating an interpretation or opinion.

#### Specimen Referral

There must be a procedure for following-up results not received in a timely fashion.

4.5.4 The accreditation status of subcontractors should be regularly reviewed to ensure currency. Information on accreditation status and scope of accreditation may be found at NATA’s website or by contacting one of NATA’s offices.

### 4.6 External Services and Supplies

Refer to Section 5.6 Assuring quality of examination procedures for requirements regarding microbiological media.

### 4.10 Corrective Action

Internal audits, accreditation assessments, customer feedback, quality control data, proficiency testing etc generate recommendations for corrective action which must be evaluated, prioritised, implemented and monitored for effectiveness. Consequently, the system for monitoring progress must be comprehensive and adequately cross-referenced. The quality manager should coordinate this system.

### 4.11 Preventive Action

Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints. Total quality management tools such as brainstorming, flowcharting, Pareto charts etc may assist this process. Consideration should also be given to providing staff with a formal mechanism for contributing suggestions for improvement.

### 4.13 Quality and Technical Records

All records must include the identity of the person making the record.

It is recognised that a number of staff may be involved in test processes or other laboratory procedures. It is the laboratory’s responsibility to identify the critical step(s) in the procedure and ensure that the identities of the staff concerned are recorded.

Retention times (including raw data) will not be less than three years or the maximum recalibration interval of equipment (whichever is the longer period). NPAAC, legislation or contractual obligation may prescribe longer retention times.

The records system must include a copy of all test reports and certificates which include results of testing covered by the accreditation, or must allow them to be reproduced.

In general, the records system must include the following:

a) the specimen identification;
b) the test document identification;
c) the date of the test;
d) the identity of the test;
e) the identity of the test equipment (if relevant);
f) original test observations and calculations;
g) the identity of the person performing the test;
h) an indication that calculations and manual data transfers have been checked;
i) details of action taken in response to unacceptable results; and
j) any other information specified in the test method, other contractual documents or relevant statutory regulations.

Alterations to data must include the date the change was made and the identity of the responsible staff member.

### 4.15 Management Review

The effectiveness of the quality system shall be reviewed by management at least once per year.

### 5 Technical Requirements

The following documents may contain specific accreditation criteria or ancillary accreditation information:

- Health Insurance (Accredited Pathology Laboratories - Approval) Principles
5.1 PERSONNEL

Staff who work only “out-of-hours” must have regular contact with routine and in particular, supervisory staff. As a guide, one day per month spent in the laboratory during normal working hours would be appropriate.

The time allocated should, however, be sufficient for the staff member to update all skills required for the out-of-hours service.

Records of the above must be available to the assessment team and must be sufficiently detailed to demonstrate compliance.

5.1.5 The number of staff required will vary from laboratory to laboratory and the adequacy of staff numbers will be determined by assessment as will the adequacy of supervision.

5.1.9 Adequate opportunity for continuing education must be provided for all staff. Any education program must include in-house and external components and there must be access to appropriate reference texts and journals.

Components of in-house education may include:
- regular educational presentations;
- journal article reviews;
- case presentations;
- review of QAP educational material; and
- review of interesting or abnormal blood films, cultures etc.

It would be expected that at least one journal and textbook should be made available by the laboratory for each area in which testing is undertaken.

Components of external continuing education may include:
- membership of relevant professional societies; and
- attendance at meetings, conferences and workshops; and such attendance must be recorded.

Training records must be maintained for all personnel. Such records must include details and dates of:
- relevant academic qualifications;
- participation in the laboratory’s training program;
- in-house and external training courses undertaken;
- conferences, seminars, workshops etc attended; and
- relevant publications.

Records must be sufficiently detailed to indicate competence in individual tests.

Proof of qualifications, membership of professional societies and hours of attendance at the laboratory may be requested as part of the assessment process.
Evidence of recognition of overseas qualifications must be available.

5.1.11 Where staff are expected to work in areas other than those in which they would normally work (eg. when on call or working on a weekend) a program of regular refresher training must be established.

5.2 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

Safety
A Safety Manual detailing the laboratory’s policies and procedures in relation to health and safety must be readily available to all staff.

The NATA/RCPA process emphasises the importance of safe laboratory practice but the review of safety during an assessment does not constitute a formal safety audit.

State and territory authorities are responsible for occupational health and safety in laboratories. Consequently NATA does not define mandatory safety measures. Nevertheless the Association does draw attention to any unsafe practices that are observed. Laboratories are encouraged to apply the relevant sections of AS/NZS 2243 Safety in laboratories. Where clauses related to safety are written into test methods covered by the accreditation, however, these must be observed. Recommendations relating to laboratory safety are listed in Section 6: Appendix A.

5.3 LABORATORY EQUIPMENT

Requirements relating to equipment calibration are detailed in Section 4: Equipment Calibration Intervals.

Immunohaematology
At time of publication, the requirements concerning off-site or external blood bank refrigerators were under discussion. The current position is as follows, however, laboratories should be vigilant for any change in this policy.

Where a laboratory is using off-site or external blood bank refrigerators to store blood intended for transfusion purposes, it should ensure that the blood units are stored and handled appropriately. A procedure should be in place to confirm and monitor the suitability of the off-site storage locations to ensure that the blood bank refrigerators are being maintained in accordance with AS 3864, Medical refrigeration equipment - For the storage of blood and blood products.

Off-site or external blood bank refrigerators must be monitored where the laboratory accepts unused cross-matched blood units back into stock.

The maintenance and monitoring provisions for blood bank refrigerators outlined in Appendices A and G of AS 3864 while informative to the manufacturer are also seen by NATA to represent the standard which should be applied by users where possible. However, it is recognised that there is a large variation in age, design and construction of blood bank refrigerators in use around the country. For some refrigerators it is not always possible to readily access temperature probes and consequently strict adherence to this aspect of Appendix A, AS 3864 may be impractical if not impossible.

The minimum requirements for monitoring are:

- a continuously monitored alarm with an audible signal, the alarm function to be checked weekly;
- a temperature recording device which is checked frequently – at least at the beginning of each shift; and
- a check of the calibration of the temperature recorder annually.

Laboratories with new refrigerators that incorporate electronic systems or other simple provision for checking the alarm points (2.5°C and 5.5°C) would in addition be expected to conduct this check on a weekly basis.

Laboratories with older refrigerators must ensure when a new replacement is planned that it conforms to the standard not only structurally and functionally but also with the monitoring recommendations in Appendix A of the standard.

5.4 PRE-EXAMINATION PROCEDURES

Specimen collection
The laboratory’s collection procedures must include:

- containers/tubes required for each test; and
- “order of draw” for multi-sampling vacuum tubes.

Where the laboratory is responsible for collection, additional information relating to patient identification, recording of patient history (where relevant) and safety precautions must be documented and readily available to collection staff.

Documented instructions must be available for self-collect specimens (eg. midstream urine, semen) in appropriate languages for the patient population.

The specimen collector must be identifiable in the laboratory records.

Specimen collection containers must not be pre-labelled.
The minimum requirements for labelling specimens are two identifiers attributable to the patient. Generally these will be patient’s full name and either date of birth or medical record number. Where point-of-care testing is performed, labelling requirements may be relaxed.

The date, and where necessary for the interpretation of test results, the time of collection must be recorded. Information which may affect the test results such as dose times, fasting/non-fasting etc must also be recorded.

Consumables in the collection area, in particular tubes containing additives, must be monitored for expiry dates.

Specimen reception

5.4.8 Documented specimen reception procedures must also cover:

a) criteria for acceptance or rejection of unsuitable specimens (eg containers leaking or broken, specimens collected into wrong containers, specimens unsuitable for the examination requested, inadequately labelled specimen containers); and

b) action to be taken in the event that an unsuitable specimen is received.

Specimens which are not labelled with patient’s full name and either date of birth or medical record number are considered to be inadequately labelled (except point-of-care testing specimens).

Where inadequately labelled specimens are received, the laboratory must assure itself of the identity of the specimen. Where the identity of the specimen cannot be assured, testing must not proceed unless the specimen is irreplaceable or critical.

If specimens that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of any subsequent action taken.

There may be special circumstances where the identity of the patient will not be revealed to the laboratory. In such cases, adequate precautions must be taken to uniquely identify the specimen at all stages.

Specimens and associated records (worksheets, slides etc) must be uniquely identified during all stages of testing. This may be achieved by the use of a unique laboratory number. This is usually the most practical option especially where large numbers of specimens are processed. Alternatively, specimens and associated records can be uniquely identified by the use of two patient identifiers (eg. patient’s name and either date of birth or medical record number).

The uniqueness of a numbering system should take into consideration the specimen storage time and the possibility of two specimens with the same number being in the laboratory at the one time.

Specimen referral

Refer to section 4.5 Examination by Referral Laboratories

5.5 EXAMINATION PROCEDURES

Guidance on test methods and related issues should be sought from the publications of the relevant professional societies.

5.5.2 Validation of methods

Validation data must be retained by the laboratory and be available for review at assessment.

Reference to NPAAC Requirements for the Validation of In-house In Vitro Diagnostic Devices (IVDs) and NATA Technical Note 17 Guidelines for the Validation and Verification of Chemical Test Methods is recommended in formulating procedures for validation.

Method documentation must be reviewed annually.

5.5.3 Methods manuals

Each procedure must be authorised and dated by the responsible staff member.

Where kit inserts are included in manuals, inserts for new batches received must be checked for changes in procedure. Where changes are identified, a copy of the new insert must be placed in the manual.

5.5.5 Reference intervals

It may be necessary for laboratories to establish their own reference intervals by statistically valid means. Alternatively, use can be made of published reference intervals. These should, however, be validated for use with the laboratory’s own patient population and methods.

Age, gender and other relevant information must be considered when establishing reference intervals.

Selection of methods

Where a test can be performed by more than one method there must be documented criteria for method selection.
5.6 Assurance of the Quality of Examination Procedures

5.6.1 Internal Quality Control

Many factors will influence the frequency with which quality control (QC) is performed. The quality control protocol must take into account these factors and be such that the laboratory has confidence in the patients' results issued. The adequacy of quality control procedures will be reviewed at assessment.

Guidance on QC issues should be sought from the publications of the relevant professional societies.

- The QC material used must cover the analytical concentrations encountered. Low/normal/high, normal/abnormal, positive/negative, reactive/non-reactive controls, as appropriate for the test, must be performed.

- The use of controls independent of those produced by the manufacturer of the test or analyser should be considered. If the laboratory uses QC from the same supplier as the calibrator, the QC must be validated independently from the calibrator.

- Where calibration of an assay is required, appropriate material must be used as a calibrator. If the material selected is not intended for use as a calibrator, assigned calibration values must be substantiated.

- Acceptable ranges (confidence limits) must be defined for internal quality control material.

- Graphical presentation of numerical QC results will assist the early detection of trends.

- The laboratory must have a system of long-term monitoring of internal quality control results to assess method performance.

Additional discipline-specific QC requirements are detailed below.

Cartridge-based instruments

These may be of the type where:

a) the complete analytical process occurs within the cartridge and the instrument functions solely as a detector and reporter of the test signal from the cartridge; or

b) the cartridge contains some or all required reagents, and the instrument participates in the generation of the test signal.

Electronic check: Where the detector is provided with an electronic means of regularly assessing satisfactory performance, such checking should be carried out at least at the frequency recommended by the manufacturer. A record of checks must be kept.

Storage of Cartridges: Cartridges must be transported and stored according to manufacturer's instructions. For each refrigerated storage site, the NATA requirement for maintaining temperature records is applicable.

QC & QA of Cartridges: For the purpose of QA and QC, the same batch/lot no. of cartridges may be treated as a single entity regardless of the number of storage sites and number of instruments using the cartridges, providing:

- the cartridges are used at the same geographic site;
- the same batch/lot number is received from the supplier in the same delivery;
- the above conditions of instrument checking and cartridge transport and storage are met;
- sufficient quality control is undertaken on each batch/lot number of cartridges to demonstrate that analytical performance is satisfactory throughout the stated shelf life; and
- a record is kept of the instrument(s) and cartridge source(s) performing the checks.

Chemical pathology

- Control material should be matrix matched (i.e. urine based controls should be used for assays of urine analytes.)

- Laboratories must determine confidence limits for acceptance of QC results, by appropriate statistical methods, using their own data. Mean, standard deviations and ranges supplied by manufacturers may not always provide adequate control of assays.

- The minimum requirement for blood gas and CO-oximetry QC is a daily assay of control material at two or more control levels, performed concurrently. For instruments with a calibration factor this procedure should take place following a full calibration cycle and before any subsequent testing of patient specimens.

Cytology

A program must be established correlating non-gynaecological cytology reports with any subsequent histopathological findings, where available, and details of this program must be documented.

Where histopathology is not performed in the same laboratory, letters should be sent to referring doctors requesting information on other investigations which have been performed on these patients. It is appreciated that in many instances responses may not be received, however, the laboratory should make every attempt to obtain the histopathological findings and correlate them with its cytopathology results.
All findings must be documented and a protocol for the review of the cytology must be established for cases where histopathological and cytopathological findings are discrepant.

The RCPA policy on the examination and reporting of non-gynaecological cytology specimens by pathologists after screening by cytotecnologists is as follows:

If the specimen is either voided urine or sputum and the screening outcome is "no malignant, atypical or other cells" the report can be issued by the laboratory (ie. it can be released by an appropriately qualified and trained cytotecnologist). In all other circumstances, the specimen together with the request, including the clinical notes and the opinion(s) of the cytotecnologist(s) must be submitted to an appropriately qualified and trained pathologist, who will examine the case and complete and sign out the report.

Haematology

- A multi-level control must be run at least once per day on automated cell counters, taking into account open and closed modes. There must also be a means of monitoring drift.

- Hemostasis (coagulation) quality control must include normal and abnormal controls at least each day testing is performed.

- Where necessary, positive controls must be performed with special stains. Control slides must be retained so that they can be retrospectively linked to the patients' slides to which they pertain.

Histopathology

- Where necessary, control slides must be performed with special stains. Control slides must be retained so that they can be retrospectively linked to the patient's slides to which they pertain.

- The identification of specimens must be secure through all stages of processing. Procedures that may be employed to minimise the risk of specimen mix-up are as follows:
  - checking of stained sections against the corresponding block prior to reporting;
  - checking slides and blocks against the details on the request form prior to reporting;
  - handling one case at a time (eg. at microtomy); and
  - labelling slides and cassettes for one case at a time.

Immunohaematology

Refer to ANZSBT Guidelines for Pretransfusion Testing.

Immunology

- A positive and negative reaction must be demonstrated as a minimum on every immunofluorescence run and as an optimum on every immunofluorescence slide. Optimally, borderline positive controls and/or controls titrating to a known endpoint should also be used.

  (Note: laboratories are able to demonstrate these reactions by either controls or patient specimens.)

- Reactive controls with defined immunofluorescent patterns for the antibodies under investigation must be tested as a minimum on every new batch of slides. Optimally, they should be tested on every run.

  (Note: Once the specificities detected by the substrate have been confirmed and the slides are stored under monitored correct conditions, and are within the expiry date, it is not essential to repeat for every run.)

- As a minimum, the appropriate working concentration of each new batch of fluorescein-labelled anti-human immunoglobulin conjugate must be determined by the checkerboard titration with each different substrate with which it will be used. Optimally, this should also be performed for every new batch of individual substrate.

  (Note: If using commercial kits this should have already been done by the manufacturer. If conjugates and slides are purchased separately from the same manufacturer, however, the assay would still need to be validated. If using conjugate from one manufacturer and slides from another or in-house slides then the conjugate dilution will need to be optimized for individual substrates.)

- Appropriate controls must be run with each ELISA plate. Optimally, non-kit controls should be included to monitor performance over time, and enable the determination of inter-lot batch variation. Appropriate negative controls/specimens should be included on each ELISA plate.

Microbiology

Media

Each laboratory is responsible for ensuring that an appropriate level of quality control is performed on the media it uses.

a) In-house media preparation and quality control

Each laboratory must maintain an effective media
preparation and quality control program designed to suit the scope of testing.

Details of the procedures for preparation and quality control must be documented as part of the laboratory quality system. (NATA Technical Note 4 Guidelines for the Quality Management of Microbiological Media and ASM Guidelines for Assuring Quality of Medical Microbiological Culture Media).

Records must be kept of the preparation details for all types of media. This must include:

- a) type of media;
- b) unique identity (batch code);
- c) date of preparation and identity of operator;
- d) volume of media/solutions made;
- e) ingredients, manufacturer, manufacturer’s batch number and quantity of each component;
- f) initial pH (pre-sterilisation);
- g) final pH (post-sterilisation);
- h) method of sterilisation, including time and temperature as appropriate;
- i) volume dispensed (if medium is used as a diluent or the volume is critical for other reasons); and
- j) volume check post-sterilisation (if medium is used as a diluent or the volume is critical for other reasons).

All media produced must be checked for performance and records maintained. Information must include:

- a) physical appearance;
- b) sterility results (including sample size); and
- c) performance checks using positive and negative control organisms (eg. biochemical reactions, morphology and recovery rates for semi-quantitative or quantitative methods).

Records of performance testing must be traceable to batch preparation records. The data generated must be used to assess the performance of each new batch against acceptance/rejection criteria.

Bulk consignments of a manufacturer’s dehydrated media of the same batch number can be checked for performance and monitored for batch to batch variation. These data can be valuable in reducing the degree of testing of daily batches of prepared media.

b) Media produced in-house for distribution to satellite laboratories

All laboratories, including satellite laboratories receiving media from parent non-accredited media facility, will be required to carry out full quality control evaluation as outlined above.

Laboratories preparing media for satellite distribution will need to seek NATA accreditation for media quality control in Biological Testing, as NATA’s Medical Testing field will no longer conduct evaluation of media quality control (except for in-house use).

c) Media purchased from NATA accredited manufacturers

NATA accredited media manufacturers are those holding NATA accreditation within the field of Biological Testing for quality control testing of media they produce. Laboratories should assure themselves that such accreditation is held by requesting the current scope of the manufacturer’s accreditation with NATA. The scope of accreditation will specify the classes of media for which the manufacturer can issue endorsed statements of quality control.

All media must be initially assessed for suitability to the particular requirements of the laboratory prior to purchase. This assessment should take into account the nature of the media and the type of test for which they are used, etc.

On an ongoing basis, some media will require only visual examination whereas other types of media (eg. selective media specified in Section 4.3 of the ASM’s Guidelines for Assuring Quality of Medical Microbiological Culture Media) require the monitoring of all batches produced until sufficient data have been generated to assure the user of the reliability of the product. At such time, the frequency of testing may be reviewed and reduced.

Manufacturers may provide a customer with either a quality control report or a compliance label on each batch of media.

When a manufacturer issues a product, the product must be labelled with the product name, batch number, date manufactured and expiry date. The customer must also be provided with details of:

- a) quality control protocols (eg. test methods, for example Miles and Misra, plate counts, CLSI, sterility protocol etc);
- b) name and code of media;
- c) purpose or scope of media;
- d) ingredients;
- e) quality control (eg. organisms, pH, etc);
- f) expected results; and
- g) shelf life.

If this information is issued on the form of a report or certificate, it should also include the NATA endorsement (as used on test reports).
Media must also be stored and used in accordance with the manufacturer’s instructions. These instructions need to be documented and include inventory control.

Laboratories must keep a log book detailing the type of media, batch number and date received.

The laboratories must also periodically review the reliability of purchased media and document the results of this review. Records relating to media quality control need to be retained by the laboratories for three years.

(d) Media from non NATA-accredited suppliers

Laboratories purchasing media from non NATA-accredited suppliers are required to perform complete quality control testing on all media. For guidance on retesting requirements, the ASM’s Guidelines for Assuring Quality of Medical Microbiological Culture Media and NATA Technical Note 4 - Guidelines for the Quality Management of Microbiological Media should be consulted.

(e) Media from suppliers holding ISO 9001 certification only

Certification of the operations of a manufacturer to ISO 9001 does not equate to NATA technical accreditation. Laboratories purchasing media from suppliers certified to ISO 9001 only or equivalent will be required to carry out complete quality control testing on all media. For guidance on retesting requirements, ASM’s Guidelines for Assuring Quality of Medical Microbiological Culture Media and NATA Technical Note 4, Guidelines for the Quality Management of Microbiological Media should be referred to.

Identification Tests/Kits

A quality control program must be established for identification tests/kits.

Antibiotic Susceptibility Testing

Quality control of antibiotic susceptibility testing must be performed in accordance with the documented method. Departures from the standard method must be validated.

Zone sizes for QC results must be recorded numerically (ie. millimetres).

The results of direct antibiotic susceptibility testing of urine may be reported provided that:

i) the method used by the laboratory is fully documented and the conditions for its use defined;

ii) the method has been validated by comparison with a standard method and relevant records retained;

iii) the laboratory’s method, if based on published data, has been validated for its own patient population and in the hands of its own staff; and

iv) a standardised method is available for use in circumstances where direct results are equivocal or there is uncertainty about reliability.

QC must be performed on microbiological identification kits (eg API) using relevant test organisms from a recognised type culture. QC should be performed when commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

Reproductive Medicine

As a minimum, a positive control must be run with every sperm antibody assay.

Serology

For some serological tests, such as those for HIV antibody, hepatitis C antibody and hepatitis B surface antigen, supplemental testing is required for reactive screening tests in persons not already known to be infected.

Virology

ASM recommends that commercial suppliers of viral culture media be NATA accredited. Laboratories should buy from NATA-accredited suppliers.

The laboratory should test each new batch of media to ensure:

- the medium grows the cell lines expected to grow;
- it produces normal densities (eg. monolayer);
- it grows in an appropriate time frame;
- it produces normal cell morphology;
- “cells and medium” support the growth of viruses or other intracellular pathogens of interest; and
- uninoculated and inoculated controls are used.

Different controls may be used for different viruses. The laboratory should be able to demonstrate that appropriate controls are being used.

Laboratories should monitor the growth of viral cell lines by the following:

- recording of split ratios for both primary and continuous cell lines;
- testing for Mycoplasma yearly; and
- setting up uninoculated (cell culture only) and inoculated (cell culture with known virus) should be routinely set up with all viral assays.
5.6.2 Estimation of uncertainty of measurement

The estimation of uncertainty of measurement (MU) applies at present to quantitative tests only. This includes those tests where a numerical value is reported as a qualitative result, such as serological assays with a “cut-off” value where the numerical result is reported as detected or not detected.

The following must now be available:

- the procedure for estimating MU;
- examples of completed estimations using the laboratory’s documented procedures; and
- a plan or schedule showing how the laboratory intends to achieve the estimation of the uncertainty of measurement for its methods.

Progress towards the completion of all uncertainty estimations will be reviewed at assessment.

Additional information is available on the NATA website as well as the ILAC (www.ilac.org) and APLAC (www.ianz.govt.nz/aplac/) websites.

5.6.3 Calibration

Requirements relating to equipment calibration in this field are detailed in Section 4: Equipment Calibration Intervals. It should be noted that calibration requirements will vary depending on method specifications. For equipment not listed, reference must be made to manufacturers’ specifications.

Test and calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement (including, where relevant, instruments used for monitoring critical environmental conditions) shall be calibrated by (one or more) of the following:

- NATA accredited calibration laboratories and the results reported on a NATA endorsed document;
- Australia’s National Measurement Institute;
- calibration laboratories accredited by one of NATA’s Mutual Recognition Agreement (MRA) partners and the results reported on an endorsed document;
- the national metrology institutes that are signatories to the CIPM MRA.

The calibration must actually be carried out by the national metrology institute. Unendorsed reports from organisations claiming traceability to a national metrology institute, or those bearing only an ISO 9000 series certification endorsement, are not acceptable.

NATA can provide information on the endorsements used by its MRA partners.

National Measurement Act

- Where measurement traceability in accordance with Section 10 of the National Measurement Act 1960 is required, the calibration of equipment must be performed by NATA accredited laboratories which use reference standards calibrated by laboratories appointed as Verifying Authorities by the National Measurement Institute under the National Measurement Regulations with the results reported on a Regulation 13 Certificate.

For example, this level of traceability may be required for balances used in laboratories.

- Where measurement traceability in accordance with Section 10 of the National Measurement Act is required, the calibration of reference standards must be performed by laboratories appointed as Verifying Authorities by the National Measurement Institute under the National Measurement Regulations with the results reported on a Regulation 13 Certificate.

For example, this level of traceability may be required for the masses used to perform intermediate checks in-house on balances.

5.6.3 Reference standards and reference materials

Microbiology

An appropriate range of organisms must be held. Cultures used by laboratories must be traceable to a recognised culture collection or accredited supplier of reference materials. Additional wild strains (eg. isolates from samples) can be used to supplement reference strains.

Subculture may be repeated up to thirty times, at the end of which the reference strains need to be subcultured from stock kept at -70 °C (CDS Users group Newsletter No 11, Dec 2001).

The stock of organisms must be maintained under appropriate long-term storage conditions and a full history, including the number of subcultures, must be retained for each organism held.

Please refer to NATA Technical Note 14 Maintenance and Preservation of Microbial Cultures in a Laboratory Culture Collection.

5.6.4 Proficiency testing (External quality assurance programs)

The laboratory must participate in external quality assurance programs (QAPs) to cover the range of tests performed, where available. Should there be no program available, laboratories are encouraged to investigate a sample exchange program with another laboratory performing similar testing.
The laboratory is encouraged to select a QAP that is part of an accredited proficiency testing provider program.

Where analysers (e.g., blood gas analysers) are located outside the laboratory a separate QAP enrolment will be required.

Regular submission of results to the program organisers is required whether or not the timing coincides with the testing of patients’ samples.

On receipt of returns from the program organisers it must be ensured that:

a) QAP performance is reviewed and discussed by the person in charge (as defined by NPAAC) and all relevant scientific staff;

b) there is evidence that the review has taken place;

c) unsatisfactory results and other deficiencies identified by the programs are addressed as a matter of priority with any action taken documented and acceptance of apparent poor performance substantiated; and

d) the implication of unsatisfactory QAP performance to patient results must be considered and a record of the considerations and action taken kept.

As far as practicable, QAP samples must be treated in the same way as patients’ samples. Additionally, all staff (including part-time and evening staff) involved in testing patients’ samples should have an opportunity to test QAP samples.

QAP enrolment requirements for multiple same-analyte instruments

See Appendix B.1

Cytopathology

In addition to the cytopathology QAP, laboratories performing gynaecological cervical cytopathology must participate in the Performance Standards set by the National Cervical Screening Program. Results from the program organisers must be reviewed and acted upon in the same way as QAP results.

Immunology

Where specific allergens and allergen mixes are performed, the laboratory must participate in external QAP on a rotational basis (as outlined by ANZSBT Guidelines). Where a laboratory has large numbers of staff, a replicate testing program must be introduced to supplement QAP participation.

5.6.6 The degree of correlation between the methods must be established and documented.

5.7 SAMPLE STORAGE

Viral Cultures

Reference laboratories must store inoculated and uninoculated viral cultures separately.

It is strongly recommended that diagnostic laboratories store inoculated and uninoculated viral cultures separately.

5.8 REPORTING OF RESULTS

5.8.3 The identification of the laboratory on the test report must include the accreditation number, for accredited laboratories.

Reports must state “serum/plasma” where both types may be tested. If a single or predominant sample type is employed, this can be shown on the report so long as there are mechanisms in place to identify exceptions. All sample types other than the routine venous plasma or serum samples must be clearly identified on reports. This includes arterial blood samples, urine, csf, fluids, stones, and assays performed on red cell or whole blood samples. Similarly, the source of the sample must be noted where this is necessary for interpretation of results (source of stone) or source of blood sample (catheterisation studies).

Each page of a multi-page document shall bear a statement of the page number and the total number of pages.

There may be statutory requirements for additional information to be included on test reports.

In instances where NATA has granted specific approval for inclusion of results of tests not covered by the scope of accreditation, the notation “NATA/RCPA accreditation does not cover the performance of this service” shall be applied.

Reports from other laboratories

A test report may include results of tests performed by another laboratory provided that the source of those test results is clearly identified on the test report. Where testing is performed within a laboratory group, the group must be able to identify the laboratory in which testing was performed.
NATA/RCPA endorsement

Accredited laboratories are encouraged to apply the NATA/RCPA endorsement for tests covered by their accreditation. The approved forms of endorsement appear in the NATA Rules. Any other endorsement must be approved by NATA’s Chief Executive. NATA/RCPA accreditation may also be referred to on request forms and other appropriate stationery under the following conditions:

i) Both the NATA and the RCPA logos must be used;
ii) Accreditation of non-accredited services must not be implied.

In addition, the NATA endorsement may need to be applied due to client request, legislation, regulation or contract requirements or in the case of calibration certificates being supplied to an accredited facility.

Additional details relating to the appropriate forms of endorsement and the reproduction of endorsed reports are provided in the relevant schedule of the NATA Rules.

The inclusion of certification body ‘marks’ (ie. logos or emblems) on test and calibration reports is a contravention of clause G.3.5.8 of JAS-ANZ Procedure No. 10 General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems.

Unendorsed reports

Where unendorsed reports are issued on work covered by the scope of accreditation, all aspects of the testing, including the reports, must meet the accreditation requirements outlined in this document.

An accredited laboratory must issue unendorsed documents reporting results for work outside its scope of accreditation. Such documents must not include the NATA/RCPA emblem, reference to the accreditation or any other reference to NATA. Refer to NATA’s Rules for details of the circumstances under which unendorsed reports must be issued.

Work on tests outside the scope of accreditation, and the associated unendorsed reports, must avoid any conflict with the proper interests of the client or the general public and avoid bringing NATA into disrepute.

Preliminary reports

NATA permits accredited Medical Testing facilities to issue preliminary test reports. Preliminary test reports may take the form of telephoned results, unconfirmed reports, ward reports etc. It may not be necessary to refer to the preliminary report on the final report. The laboratory must have a documented protocol for issuing preliminary test reports.

Where the result is conveyed verbally, a record must be kept of the time and date of the report, recipient of the report and the reporting staff member. It must be clear which results have been reported.

5.8.14 It is common practice for pathology laboratories to receive telephone enquires regarding test results. The laboratory must have a documented protocol for the handling and recording of such enquiries.

The availability of results on computer to external enquirers must be restricted.

If preliminary laboratory results are accessible to an enquirer via a computer terminal, the status of the results (ie unvalidated, unconfirmed) must be apparent to the enquirer.

Electronic transmission of results

Test reports may be electronically issued (including from a site other than the accredited laboratory) provided that the reports have been appropriately authorised for release. The adequacy of such arrangements will be reviewed at assessment.

Copies (hard copy or computer records) of test reports must be retained at the accredited laboratory. Care must be taken to ensure that copies of handwritten comments are also retained by the issuing laboratory.

The laboratory must be able to demonstrate appropriate controls over the electronic generation, access, storage and back-up of results and reports and program controls such as password protection. If the report is to be accessed from a web site by the client there must be an appropriate control in place to ensure the report can only be downloaded in a protected format.

Any information normally included in a hardcopy report must be included on the electronically transmitted version and appear in any hard copy printed by the recipient. Flexible pagination may also be required to accommodate formatting changes when printed by the recipient.

5.8.15/.16 Amendments to test reports and calibration certificates

When, after the issuing of a test report, test data are found to be invalid, the original report shall be withdrawn and replaced by a report which is clearly identified as a replacement report.
SECTION 4: EQUIPMENT CALIBRATION INTERVALS

This section details equipment calibration requirements and the requirements for intermediate checks of equipment used in Medical Testing Laboratories.

DEFINITIONS

“Calibration” is a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand. (VIM-6.13 reference)

“Check” is a measurement of at least one point in a range of a measuring instrument or system or material against a known value to confirm that it has not deviated significantly from its original calibrated value. It is also an examination of the condition of an artefact to determine that it has not been adversely affected by constant use.

Laboratory equipment calibration and check programs should cover:

a) commissioning of new equipment (including initial calibration and checks after installation);

b) operational checking (checking during use with reference standards or reference materials);

c) periodic checking (interim but more extensive checking, possibly including partial calibration);

d) scheduled maintenance by in-house or specialist contractors;

e) complete recalibration.

The following table lists the normal periods between successive calibrations for common items of testing equipment. It must be stressed that these periods are generally considered to be the maxima appropriate in each case based on the assumption that:

a) the equipment is of good quality, of proven adequate stability, and is properly housed and used;

b) the laboratory has both the equipment capability and staff expertise to perform the requisite in-house checks;

c) all of the subsidiary checks indicate satisfactory operation.

Reduction of calibration intervals

Reduced intervals between calibrations and/or checks are required when the equipment operates under less than ideal conditions. If any suspicion of damage arises the equipment must be recalibrated immediately and thereafter at reduced intervals until it is shown that stability has not been impaired.

Reduced intervals between calibrations and/or checks may also be required in particular testing applications or with particular equipment configurations.

Extension of calibration intervals

The Association will consider submissions for the extension of calibration intervals based on factors such as history of stability, frequency of use, accuracy required, ability of staff to perform in-house checks and successful participation in proficiency testing programs. In recognising that calibration costs are often considerable, the Association encourages laboratories to take this process further by developing laboratory equipment assurance programs. These programs move the emphasis from a dominant reliance on demonstration of equipment conformance at the time of calibration to a greater contribution from more frequent checks against measurement devices or reference materials, as well as cross-checks against similar systems and the checking of particular critical features.

Laboratories are invited to develop their own programs that optimise the expense of calibration and checking against the assurance of measuring equipment accuracy. This may lead to extensions of the intervals between complete recalibration by external calibration services.
**CALIBRATION OF COMMON TEST EQUIPMENT**

The following are requirements for frequency of recalibration and checks on test equipment with reference to specific calibration and check procedures that must be adhered to. As discussed earlier, the time intervals indicated are maximum intervals and are dependent on the accuracy required and the type of use the instrument is exposed to. In general, the calibrations are carried out by an external calibrating authority and an endorsed test report is obtained for this work. If a laboratory has the capabilities to carry out these calibrations in-house they must demonstrate the capability to do so according to the criteria set out in NATA Policy Circular No. 12 and NATA Technical Note No. 28. Checks are normally carried out in-house by the laboratory staff. If however, the checks are carried out by an external authority then an endorsed test report must be obtained.

<table>
<thead>
<tr>
<th>ITEM OF EQUIPMENT</th>
<th>calibration interval (years)</th>
<th>checking interval (months)</th>
<th>procedures and references</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTOCLAVES</td>
<td></td>
<td></td>
<td>NATA Technical Note 5</td>
</tr>
<tr>
<td>BALANCES</td>
<td>3</td>
<td>12</td>
<td>NATA accredited laboratory or service. Where the laboratory can demonstrate that the balance is used in a suitable environment (eg. dust free, chemical free) AND results of user checks consistently demonstrate good performance and ability, this requirement may be waived.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6 Repeatability check. The Calibration of Weights and Balances</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EC Morris and KMK Fen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NATA Technical Note 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 One point check. The Calibration of Weights and Balances</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EC Morris and KMK Fen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NATA Technical Note 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Zero point check.</td>
</tr>
<tr>
<td>BIOLOGICAL SAFETY CABINETS</td>
<td>12</td>
<td></td>
<td>NATA accredited laboratory</td>
</tr>
<tr>
<td>CENTRIFUGES</td>
<td>12</td>
<td></td>
<td>Tachometer (mechanical stroboscope or light cell type) where operating speed is specified. Calibration of the timing device and, where appropriate, the temperature measurement device will also be required. In addition, performance testing is recommended for specific applications.</td>
</tr>
<tr>
<td>FUME CUPBOARDS (CABINETS)</td>
<td>12</td>
<td></td>
<td>NATA accredited laboratory</td>
</tr>
<tr>
<td>MASSES</td>
<td>3 initial then 6 subsequent</td>
<td></td>
<td>NATA accredited laboratory</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NATA accredited laboratory</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NATA accredited laboratory</td>
</tr>
<tr>
<td>ITEM OF EQUIPMENT</td>
<td>calibration interval (years)</td>
<td>checking interval (months)</td>
<td>procedures and references</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------</td>
<td>----------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MICROPLATE ABSORBANCE READER</td>
<td></td>
<td></td>
<td>A standardised plate traceable to a recognised calibration authority must be run at least annually but preferably six-monthly. For older plate readers that do not have a self checking system built in, the standardised absorbance plate may need to be run more frequently.</td>
</tr>
<tr>
<td>pH METERS</td>
<td>Daily or on use</td>
<td></td>
<td>Check against two buffer solutions.</td>
</tr>
<tr>
<td>PISTON OPERATED VOLUMETRIC APPARATUS</td>
<td>Initial 3</td>
<td></td>
<td>Check volume delivered AS 2162.2 Check the volume delivered at the settings in use*.</td>
</tr>
<tr>
<td>SPECTROPHOTOMETERS</td>
<td>3</td>
<td></td>
<td>Check wavelength accuracy, bandpass, absorbance, straylight error, linearity of response, repeatability and matching of cells. Prepare new calibration curve.</td>
</tr>
<tr>
<td>TEMPERATURE (DIGITAL) INDICATING SYSTEM</td>
<td>1</td>
<td></td>
<td>Calibrate against a reference temperature measuring system.</td>
</tr>
<tr>
<td>(hand-held, bench type and temperature loggers)</td>
<td>Initial</td>
<td></td>
<td>Check efficacy of automatic cold junction compensation with the temperature sensor at the ice point.</td>
</tr>
<tr>
<td>THERMOMETERS</td>
<td></td>
<td></td>
<td>Check at ice point.</td>
</tr>
<tr>
<td>Reference</td>
<td>10</td>
<td>Before use</td>
<td>NATA accredited laboratory Check at ice point.</td>
</tr>
<tr>
<td>Working-liquid-in-glass</td>
<td>10*</td>
<td></td>
<td>NATA accredited laboratory Check at ice point</td>
</tr>
<tr>
<td></td>
<td>6*</td>
<td></td>
<td>NATA Technical Note 19</td>
</tr>
<tr>
<td>Working-digital</td>
<td>1</td>
<td></td>
<td>NATA accredited laboratory Check at ice point or one point in working range</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td></td>
<td>NATA accredited laboratory Check at ice point or at one point in the working range against a reference thermometer.</td>
</tr>
</tbody>
</table>

* If there is no reference thermometer
* Where a multi-channeled pipette is used, at least two barrels must be checked every three months with the channels rotated so that all channels are checked within a twelve month period.
The following is a list of major analytical instrumentation that can be calibrated primarily in-house by use of reference materials of known composition.

**Chromatographs**

a) **Gas chromatographs**

Instrument performance must be routinely monitored during use with reference materials. System components (eg integrators, ovens, electronic amplifiers and detectors) must also be checked periodically, and records kept.

b) **Liquid chromatography**, including **high performance (or high pressure) liquid chromatographs (HPLC)** and **ion chromatography**

The total system must be monitored during use with reference materials. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (eg pumping system and detectors) must be subject to periodic checks and details must be recorded.

The following section details general checks and maintenance requirements for equipment and instrumentation in Medical Testing laboratories.

**Flow Cytometry**

Performance of the photomultiplier tubes should be monitored daily to ensure that the correct alignment is maintained between calibrations and that the settings in use are still within the monthly calibration parameter. For Coulter flow cytometers, “immunochek” QC beads are used. To align the photomultiplier, calibration beads such as flowcheck beads are used. The alignment must be performed in line with the manufacturer’s recommendations (ie. monthly) and following any instrument relocation.

<table>
<thead>
<tr>
<th>ITEM OF EQUIPMENT</th>
<th>calibration interval (years)</th>
<th>checking interval (months)</th>
<th>procedures and references</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TIMING DEVICES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop watches, clocks</td>
<td></td>
<td>6</td>
<td>Test aurally against the Telstra clock (Australia). Two measurements separated by at least one hour must be carried out.</td>
</tr>
<tr>
<td><strong>VOLUMETRIC GLASSWARE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipettes, burettes, flasks, distillation receivers</td>
<td>Initial</td>
<td></td>
<td>AS 2162.1, BS 1797</td>
</tr>
</tbody>
</table>

**Microscopes**

Regular cleaning and maintenance of microscopes is essential for satisfactory operation. The stage and lenses must be cleaned after use and maintenance and servicing must be carried out by competent personnel.

**Temperature-controlled equipment**

The performance of waterbaths, incubators, ovens and refrigerators must be monitored to ensure compliance with the temperature requirements of test methods and manufacturer’s storage requirements.

Accordingly, daily recorded checks of the temperature within the load space of these items of equipment must be maintained. The use of continuous temperature monitors is strongly recommended where temperature control is critical. Maximum/minimum thermometers should be used as appropriate.

The thermometers used to monitor the performance of temperature-controlled equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods.
### SECTION 5: CLASSES OF TEST

Accreditation in the field of Medical Testing is described by classes and sub-classes of test.

These classes and sub-classes are fixed descriptors, free text being used to qualify or amplify terms as necessary. Where the scope of testing of a laboratory cannot be adequately described by existing descriptors, the Medical Testing Accreditation Advisory Committee may from time to time establish new classes and/or sub-classes of test.

Classes of Test are revised from time to time. For the most current version please contact a NATA office or visit the NATA website.

<table>
<thead>
<tr>
<th>10.10</th>
<th>Microbiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Preparation of films for microscopic examination</td>
</tr>
<tr>
<td>.02</td>
<td>Inoculation of cultures</td>
</tr>
<tr>
<td>.03</td>
<td>Microscopic examination of clinical specimens</td>
</tr>
<tr>
<td>.04</td>
<td>Identification of organisms including antibiotic susceptibility testing</td>
</tr>
<tr>
<td>.05</td>
<td>Identification of organisms excluding antibiotic susceptibility testing</td>
</tr>
<tr>
<td>.06</td>
<td>Detection of bacterial antigens</td>
</tr>
<tr>
<td>.07</td>
<td>Specialised antibiotic procedures</td>
</tr>
<tr>
<td>.08</td>
<td>Detection and characterisation of microbial DNA/RNA</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.11</th>
<th>Bacteriology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Preparation of films for microscopic examination</td>
</tr>
<tr>
<td>.02</td>
<td>Inoculation of cultures</td>
</tr>
<tr>
<td>.03</td>
<td>Microscopic examination of clinical specimens</td>
</tr>
<tr>
<td>.04</td>
<td>Identification of organisms including antibiotic susceptibility testing</td>
</tr>
<tr>
<td>.05</td>
<td>Identification of organisms excluding antibiotic susceptibility testing</td>
</tr>
<tr>
<td>.06</td>
<td>Detection of bacterial antigens</td>
</tr>
<tr>
<td>.07</td>
<td>Specialised antibiotic procedures</td>
</tr>
<tr>
<td>.08</td>
<td>Detection and characterisation of microbial DNA/RNA</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.12</th>
<th>Parasitology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Preparation and examination of films</td>
</tr>
<tr>
<td>.02</td>
<td>Definitive identification of parasites</td>
</tr>
<tr>
<td>.03</td>
<td>Detection and characterisation of parasitic DNA/RNA</td>
</tr>
<tr>
<td>.04</td>
<td>Detection of parasitic antigens</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.13</th>
<th>Virology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Non-cultural methods of detection</td>
</tr>
<tr>
<td>.02</td>
<td>Isolation of viruses</td>
</tr>
<tr>
<td>.03</td>
<td>Definitive identification of viruses</td>
</tr>
<tr>
<td>.04</td>
<td>Detection and characterisation of viral DNA/RNA</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.14</th>
<th>Mycology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Microscopic examination of clinical specimens</td>
</tr>
<tr>
<td>.02</td>
<td>Culture of specimens</td>
</tr>
<tr>
<td>.03</td>
<td>Limited identification of isolates</td>
</tr>
<tr>
<td>.04</td>
<td>Definitive identification of isolates</td>
</tr>
<tr>
<td>.05</td>
<td>Susceptibility to antifungal agents</td>
</tr>
<tr>
<td>.06</td>
<td>Detection and characterisation of fungal DNA/RNA</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.15</th>
<th>Mycobacteriology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Microscopic examination of clinical specimens</td>
</tr>
<tr>
<td>.02</td>
<td>Culture for isolation of mycobacteria</td>
</tr>
<tr>
<td>.03</td>
<td>Limited identification of isolates</td>
</tr>
<tr>
<td>.04</td>
<td>Definitive identification of isolates</td>
</tr>
<tr>
<td>.05</td>
<td>Susceptibility testing</td>
</tr>
<tr>
<td>.06</td>
<td>Detection and characterisation of mycobacterial DNA/RNA</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.16</th>
<th>Serology of infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Limited serological testing</td>
</tr>
<tr>
<td>.02</td>
<td>General serological testing</td>
</tr>
<tr>
<td>.03</td>
<td>Specialised or uncommon serological testing procedures</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.19</th>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Semen analysis (Screening Test)</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.20</th>
<th>Immunohaematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Blood grouping including ABO, Rh(D)</td>
</tr>
<tr>
<td>.03</td>
<td>Blood group antibody screen</td>
</tr>
<tr>
<td>.04</td>
<td>Identification of blood group antibodies</td>
</tr>
<tr>
<td>.05</td>
<td>Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions</td>
</tr>
<tr>
<td>.06</td>
<td>Red cell phenotyping</td>
</tr>
<tr>
<td>.07</td>
<td>Antibody elution</td>
</tr>
<tr>
<td>.10</td>
<td>Storage and distribution of blood and blood components</td>
</tr>
<tr>
<td>.13</td>
<td>Collection and storage of blood for autologous transfusions</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.30</th>
<th>Haematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Blood counts</td>
</tr>
<tr>
<td>.02</td>
<td>Visual examination of blood films</td>
</tr>
<tr>
<td>.03</td>
<td>Erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>.05</td>
<td>Automated differential leucocyte counts</td>
</tr>
<tr>
<td>.06</td>
<td>Automated reticulocyte counts</td>
</tr>
<tr>
<td>.08</td>
<td>Blood film examinations involving special staining procedures</td>
</tr>
<tr>
<td>.09</td>
<td>Examination for malarial parasites</td>
</tr>
<tr>
<td>.20</td>
<td>Bone marrow examination</td>
</tr>
<tr>
<td>.25</td>
<td>Progenitor cell transplantation procedures</td>
</tr>
<tr>
<td>.30</td>
<td>Tests for haemoglobin variants and thalassaemia</td>
</tr>
<tr>
<td>.31</td>
<td>Tests for foetal Hb</td>
</tr>
<tr>
<td>.35</td>
<td>Tests to investigate haemolysis</td>
</tr>
<tr>
<td>.36</td>
<td>Screening tests for G6PD deficiency</td>
</tr>
<tr>
<td>.37</td>
<td>Red cell enzyme assays</td>
</tr>
<tr>
<td>.40</td>
<td>Limited haemostasis related tests</td>
</tr>
<tr>
<td>.41</td>
<td>General haemostasis related tests</td>
</tr>
<tr>
<td>.45</td>
<td>Tests of platelet function</td>
</tr>
<tr>
<td>.51</td>
<td>In vivo radioisotopic haematological tests</td>
</tr>
<tr>
<td>.55</td>
<td>Iron studies</td>
</tr>
<tr>
<td>.57</td>
<td>Screening test for infectious mononucleosis</td>
</tr>
<tr>
<td>.58</td>
<td>Vitamin B₁₂ and folate (serum and red cell)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10.30</th>
<th>Haematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Blood counts</td>
</tr>
<tr>
<td>.02</td>
<td>Visual examination of blood films</td>
</tr>
<tr>
<td>.03</td>
<td>Erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>.05</td>
<td>Automated differential leucocyte counts</td>
</tr>
<tr>
<td>.06</td>
<td>Automated reticulocyte counts</td>
</tr>
<tr>
<td>.08</td>
<td>Blood film examinations involving special staining procedures</td>
</tr>
<tr>
<td>.09</td>
<td>Examination for malarial parasites</td>
</tr>
<tr>
<td>.20</td>
<td>Bone marrow examination</td>
</tr>
<tr>
<td>.25</td>
<td>Progenitor cell transplantation procedures</td>
</tr>
<tr>
<td>.30</td>
<td>Tests for haemoglobin variants and thalassaemia</td>
</tr>
<tr>
<td>.31</td>
<td>Tests for foetal Hb</td>
</tr>
<tr>
<td>.35</td>
<td>Tests to investigate haemolysis</td>
</tr>
<tr>
<td>.36</td>
<td>Screening tests for G6PD deficiency</td>
</tr>
<tr>
<td>.37</td>
<td>Red cell enzyme assays</td>
</tr>
<tr>
<td>.40</td>
<td>Limited haemostasis related tests</td>
</tr>
<tr>
<td>.41</td>
<td>General haemostasis related tests</td>
</tr>
<tr>
<td>.45</td>
<td>Tests of platelet function</td>
</tr>
<tr>
<td>.51</td>
<td>In vivo radioisotopic haematological tests</td>
</tr>
<tr>
<td>.55</td>
<td>Iron studies</td>
</tr>
<tr>
<td>.57</td>
<td>Screening test for infectious mononucleosis</td>
</tr>
<tr>
<td>.58</td>
<td>Vitamin B₁₂ and folate (serum and red cell)</td>
</tr>
</tbody>
</table>
### 10.40 Immunology

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Quantitative investigation of immunoglobulins G, A, M and D in body fluids</td>
</tr>
<tr>
<td>.02</td>
<td>Qualitative investigation of immunoglobulins G, A, M and D in body fluids including paraprotein typing, CSF oligoclonal bands and Bence Jones proteins</td>
</tr>
<tr>
<td>.06</td>
<td>Investigation of complement</td>
</tr>
<tr>
<td>.10</td>
<td>Rheumatoid factor - quantitative assays</td>
</tr>
<tr>
<td>.12</td>
<td>Detection of autoantibodies in body fluids and biopsy material</td>
</tr>
<tr>
<td>.20</td>
<td>Tests of cellular immunity - quantitation of lymphocytes</td>
</tr>
<tr>
<td>.22</td>
<td>Tests of cellular immunity - delayed hypersensitivity skin tests</td>
</tr>
<tr>
<td>.24</td>
<td>Tests of cellular immunity - in vitro lymphocyte function tests</td>
</tr>
<tr>
<td>.26</td>
<td>Tests of cellular immunity - lymphokine assays</td>
</tr>
<tr>
<td>.32</td>
<td>Assessment of neutrophils and monocytes - quantitation</td>
</tr>
<tr>
<td>.34</td>
<td>Natural killer cell assay by radioisotope release from target cells</td>
</tr>
<tr>
<td>.36</td>
<td>Cell markers</td>
</tr>
<tr>
<td>.40</td>
<td>HLA - B27</td>
</tr>
<tr>
<td>.50</td>
<td>Total IgE</td>
</tr>
<tr>
<td>.51</td>
<td>Allergen - specific IgE</td>
</tr>
<tr>
<td>.52</td>
<td>Eosinophil cationic protein</td>
</tr>
<tr>
<td>.54</td>
<td>Tryptase</td>
</tr>
<tr>
<td>.55</td>
<td>Detection of immune complexes in body fluids and biopsy material</td>
</tr>
<tr>
<td>.60</td>
<td>Simple slide tests for biochemical and immunological analytes</td>
</tr>
<tr>
<td>.70</td>
<td>Cytokines</td>
</tr>
<tr>
<td>.80</td>
<td>Molecular genetic studies</td>
</tr>
<tr>
<td>.99</td>
<td>Miscellaneous tests</td>
</tr>
</tbody>
</table>

### 10.50 Anatomical pathology

### 10.51 Histopathology

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Histopathology of biopsy material</td>
</tr>
<tr>
<td>.02</td>
<td>Immediate frozen section diagnosis</td>
</tr>
<tr>
<td>.03</td>
<td>Immunohistochemical investigation</td>
</tr>
</tbody>
</table>

### 10.52 Cytopathology

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>.01</td>
<td>Gynaecological (cervical)</td>
</tr>
<tr>
<td>.02</td>
<td>Non-gynaecological</td>
</tr>
<tr>
<td>.03</td>
<td>Fine needle aspiration biopsy specimens</td>
</tr>
<tr>
<td>.04</td>
<td>Gynaecological (other than cervical)</td>
</tr>
<tr>
<td>.05</td>
<td>Gynaecological (ovary)</td>
</tr>
<tr>
<td>.06</td>
<td>Gynaecological (uterus)</td>
</tr>
</tbody>
</table>

### 10.54 Examination by electron microscopy

### 10.56 Autopsy service

### 10.57 Autopsy facilities

### 10.59 Miscellaneous tests
ISO 15189 APPLICATION DOCUMENT

medical testing

10.62 Biochemical genetics
- .01 Metabolite analysis
- .02 Enzymology
- .03 Newborn screening
- .04 Long term storage of tissue cultures
- .05 Tissue culture and long term storage

10.70 Genetic testing

10.71 Cytogenetics
- .01 Blood
- .02 Bone marrow
- .03 Amniotic fluid
- .04 Chorionic villus tissue
- .06 Other tissues - non malignant
- .20 Other tissues – malignant
- .25 Fluorescent In-Situ Hybridisation
- .99 Miscellaneous tests

10.75 Molecular genetics
- .05 Assay for unidentified pathogenic variant(s)
- .06 Assay for identified pathogenic variant(s)
- .07 Prenatal testing
- .08 Risk calculation by indirect method
- .09 Complex linkage analysis
- .10 DNA sequencing
- .11 DNA extraction
- .12 DNA banking
- .99 Miscellaneous tests

10.76 Molecular pathology
- .01 Assay for somatic variants in DNA sequence(s)
- .02 Microsatellite instability testing
- .03 Chimerism studies
- .04 Assay for somatic variants in gene structure
- .99 Miscellaneous tests

10.80 Blood transfusion service
- .01 Collection of blood from donors, routine
- .02 Collection and storage of autologous blood donations
- .03 Collection and storage of directed/dedicated blood donations
- .04 Collection of cells or plasma by automated means
- .05 Therapeutic venesection
- .06 Operation of a mobile collection unit
- .10 Preparation of blood components
- .11 Storage and distribution of blood and blood components
- .12 Freezing and thawing of cellular components for transfusion
- .13 Preparation of leucocyte-poor red cells
- .20 Blood grouping including ABO, Rh(D) and other antigens by automated methods
- .22 Examination of serum for Rh(D) and other blood group antibodies at reference laboratory level
- .23 Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions at reference laboratory level
- .25 Automated blood grouping and antibody screening
- .35 Screening of donor blood for markers of transfusion transmitted disease
- .80 Tissue typing
- .99 Miscellaneous tests

10.90 Medical practice pathology
- .01 Analytes available on the DT60 analyser
- .02 Analytes available on the Reflotron analyser
- .03 Analytes available on the Vision analyser
- .10 Haemoglobin
- .15 Dipstick urine chemistry
- .16 Dipslide culture
- .17 Rapid streptococcal identification test
- .20 Urine pregnancy test
- .21 Serum pregnancy test
- .25 Screening test for infectious mononucleosis
- .26 Screening test for rheumatoid factor
- .50 Microbiology
- .60 Haematology
- .70 Chemical pathology
- .99 Miscellaneous tests

10.95 Assisted reproduction procedures
- .01 Semen analysis
- .02 In Vitro Fertilisation (IVF) procedures
- .03 Gamete Intracellular Transfer (GIFT) procedures
- .04 Zygote Intracellular Transfer (ZIFT) procedures
- .05 Intracytoplasmic sperm injection (ICSI) techniques
- .06 Sperm antibodies
- .07 Detection of leucocytes in semen
- .08 Sperm preparation for In Vitro Fertilisation
- .09 Embryo and semen cryopreservation
- .12 Tests for semen/sperm-cervical mucus interaction
- .99 Miscellaneous
SECTION 6: APPENDICES

APPENDIX A: SAFETY

This appendix sets out additional safety criteria for any laboratory accredited, or seeking accreditation. This list is not exhaustive, however, and laboratories must apprise themselves of any relevant Commonwealth or State requirements relating to safety. The NATA/RCPA assessment cannot be considered to constitute a safety audit and the main emphasis will be on safety of laboratory procedures.

Safety manual

Examples of procedures for inclusion in the Safety Manual include:

- procedures for handling biological, chemical and radioactive spills;
- procedures (including follow-up procedures such as counselling) for dealing with needlestick injuries;
- evacuation procedures including a plan of the facility showing the location of safety equipment and fire extinguishers;
- a policy on the use of protective clothing (e.g. gowns/coats, gloves, goggles, etc.);
- a policy prohibiting eating, drinking, applying cosmetics, etc. in the laboratory;
- routine cleaning and disinfection procedures for benches/floors and equipment such as centrifuges, microtomes, refrigerators, etc;
- any special procedures for handling hazardous substances;
- waste disposal procedures;
- the immunisation policy.

Incident register

A register should be maintained which details the nature of the incident/injury/accident and the follow-up action(s) taken.

Laboratory personnel

Personal protective clothing/equipment must be available at all times. The nature of these items will be dependent on the work being undertaken. As a minimum, laboratory coats/gowns and disposable gloves should be available. Other items may include:

- rubber gloves;
- heat/cold resistant gloves;
- eye goggles;
- face masks;
- plastic/rubber aprons.

Where radioactive work is performed, detectors must be used regularly to monitor radioactivity levels. The wearing of film badges by staff may be necessary.

Appropriate handwashing and hand-drying facilities must be available.

- Handbasins should not be fitted with domestic taps but with a suitable alternative (e.g. elbow or foot activated devices).
- The use of communal towels is discouraged. Single-use towels or automatic hand-drying devices are preferred.
- A suitable hand cleansing agent should be available.

A safety shower must be available in close proximity to all staff and its operation should be checked on a regular basis.

Eyewash solutions or eyewash stations must be available in close proximity to all staff. If commercial eyewash preparations are used, it should be ensured that the solutions are within their expiry dates.

Accommodation

Laboratories are expected to comply with any relevant statutory requirements. As these vary between states, consideration should be given to the following:

- appropriate fire extinguishing devices should be available; and
- smoke/fire detectors and fire alarms should be installed.

Signs should be present to:

- identify safety equipment such as fire extinguishers, showers, eyewash facilities;
- identify hazards and hazardous activities; and
- delineate public areas from areas of restricted access.

Gas cylinders should be secured. Acetylene storage should be outside the laboratory.

Spill kits should be available for acids, solvents, etc.

A biological safety cabinet (BSC) must be present for the handling of fresh tissue and sputum specimens.

Procedures for the cleaning and disinfection of laboratory work areas and equipment will vary depending on the microorganisms encountered.

The reagents most commonly used for such purposes include hypochlorite, alcohol and phenolics. Procedures for cleaning and disinfection should take into account the organisms likely to be encountered and the composition of the work areas and the equipment in use.
Laboratories should also consider the recommendations of relevant government bodies.

Bench and floor surfaces should be appropriate for the work being performed.

Corridors should not be used to store equipment and evacuation routes must always be kept clear.

The use of ether is discouraged. Where possible, suitable alternatives should be used.

The explosive nature of chemicals such as azides and picric acid should be noted and appropriate precautions taken.

**Equipment**

Centrifuges used for the centrifugation of biological material should have sealed buckets or a sealed rotor.

**Storage**

Specimens/samples referred to other laboratories must be transported in accordance with Australia Post, IATA, NPAAC or other relevant requirements.

Foodstuffs must not be stored in laboratory refrigerators/freezers.

Care should be taken with the storage of hazardous chemicals/substances:

- A flammable liquids storage cabinet is recommended for all but small volumes.
- Acids and solvents should not be stored together.
- It may be necessary to store some chemicals/substances in locked cabinets/cupboards.
- Storage on high shelves is discouraged.
- Suitable carriers should be available for staff who are required to carry large bottles.

Adequate ventilation should be provided in areas where chemicals such as xylene, formalin, etc. are used.

**Waste disposal**

The laboratory must have a documented waste management program which includes procedures for the disposal of:

- biological waste;
- sharps and broken glass;
- “uncontaminated” waste, eg paper waste;
- radioactive waste.

**APPENDIX B: QAP ENROLMENT REQUIREMENTS FOR MULTIPLE SAME-ANALYTE INSTRUMENTS**

Diagnostic clinical chemistry methods routinely generate in-house quality control data that reflect the variable biochemical, electro-mechanical and human factors that combine to define their current in-service analytical performance. External QAPs additionally offer medical testing facilities the opportunity of checking the performance of their in-house quality control program, additional data to assist identifying the causes of unacceptable performance, and independent audits of the analytical quality of the testing services through comparison against self and an external peer group over time.

Considerations of clinical need, workload, patient population, costs etc., may necessitate a laboratory facility employing more than one of the same, or different, analytical systems to measure the same analyte at the same or different locations. Quality assurance data demonstrate that even with identical methods and instrumentation, a variable such as location can impact measurably on analytical performance, presumably through factors such as differing work and equipment maintenance practices, staff skills, and environmental and reagent storage conditions. Therefore, in principle, every in-service analytical system should be individually enrolled in an appropriate external QAP so as to provide independent audit of its unique analytical performance.

However, in the situation where a laboratory employs more than one semi-automated instrument to measure the same analyte(s) in the same specimen type, a request for waiver of the requirement for enrolment of each such instrument in an external QAP may be approved under the following conditions.

- The analysers should be of the same manufacture, employ the same analytical principles, reagent formulations and calibrators, and be located within the same laboratory site.
- For blood gas analysers, different models of the same manufacture must employ the same sampling and sample pathway system, and must be located at the same laboratory or hospital site.
- One of the analysers in the waiver group must be enrolled in the QAP for the analytes subject to waiver.
- The non-enrolled instrument(s) in the waiver group must be subject to quality control, correlation and any other appropriate procedures sufficient to continuously demonstrate that its (their) quality assurance performance does not differ significantly from that of the enrolled instrument.
- A waiver will apply only to the analytes replicated across the instruments in the group.

- It is the responsibility of the laboratory to demonstrate that the analytical quality of each analyte measured by each instrument in the waiver group is continuously traceable to a recognised QAP.

The adequacy of the compliance arrangements will be evaluated at assessment. Additional time taken to evaluate correlation data will be at cost to the laboratory.

* The prime purpose of quality assurance is the independent assessment of analytical performance by a discrete system for the measurement of an analyte and comparison of the performance with an external peer method group. As evidenced by end-of-cycle summaries, significant variability to the bias and imprecision in the measurement of an analyte is introduced by the use of instruments of different manufacture, of methods of different analytical principle, of different reagents and calibrators. Extreme differences may especially be observed with the use of different antibodies for the measurement of the same analyte. Significant variability in analytical performance may also be introduced into identical analytical systems by different laboratory environments where consumable storage conditions, staff training and operational practices may differ.

It is a current requirement that each Approved Pathology Laboratory (APL) be individually enrolled in appropriate quality assurance programs.

* Blood gas analysers, including different models from the same manufacturer, may utilise different methods for accessing samples e.g. by drawing and by injection. Analysers may also employ different sample path-lengths between sample accession and gas measurement. Such differences can cause significant variations in reported pO$_2$ tensions at the point of measurement.

Regardless of the number of instruments, a single enrolment in an appropriate QAP is satisfactory, providing the conditions detailed under Quality Control are met.
SECTION 7: REFERENCES

NPAAC PUBLICATIONS

Guidelines for Approved Pathology Collection Centres
Guidelines for Cytogenetics Laboratories
Guidelines for Data Communication
Guidelines for Laboratory Procedures Related to the Processing, Storage and Infusion of Cells for Transplantation or Cell Therapy
Guidelines for Quality Systems in Medical Laboratories
Guidelines for Retention of Laboratory Records and Diagnostic Material
Guidelines for the Facilities and Operation of Hospital and Forensic Mortuaries
Guidelines for the Performance of Pathology Surgical Cut-up
Guidelines for the Use of Fluid Based Collection Systems and Automated and Semi-automated Screening Devices in the Practice of Gynaecological (Cervical) Cytology
Information on the Transport of Pathology Specimens
Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques
Performance Measures for Australian Laboratories Reporting Cervical Cytology
Requirements for Gynaecological (Cervical) Cytology
Requirements for Supervision of Pathology Laboratories
Requirements for the Validation of In-house In Vitro Diagnostic Devices (IVDs)
Standards for Pathology Laboratories
Standards for Pathology Laboratory Participation in External Proficiency Testing Programs

TECHNICAL NOTES

NATA Technical Note 4
Guidelines for the Quality Management of Microbiological Media
NATA Technical Note 5
Monitoring of Laboratory Steam Sterilisers
NATA Technical Note 13
User Checks of Balance Calibration
NATA Technical Note 14
Maintenance and Preservation of Microbial Cultures in a Laboratory Culture Collection
NATA Technical Note 17
Guidelines for the Validation and Verification of Chemical Test Methods
NATA Technical Note 19
Liquid in Glass Thermometers – Selection, Use and Calibration Checks
NATA Technical Note 21
Laboratory pH Meters – Calibration and Electrode Performance Checks
NATA Technical Note 27
Internal Audits and Management Review
NATA Technical Note 28
In-house Calibrations and Measurement Uncertainty

OTHER STANDARDS

AS 1216 Class Labels for Dangerous Goods
AS 2162.1 Verification and use of volumetric apparatus - Part 1 - General - Volumetric glassware.
AS 2162.2 Verification and use of volumetric apparatus – Part 2 - Guide to the use of piston operated volumetric apparatus (POVA)
AS 2243 Parts 1 to 10 Safety in laboratories
AS 2252 Parts 1 and 2 Biological safety cabinets
AS 2647 Biological safety cabinets - Installation and use
ASTM E617-91 Standard Specification for Laboratory Weights and Precision Mass Standards
BS 1797 Schedule for tables for use in the calibration of volumetric glassware
ISO/IEC 17025 General Requirements for the Competence of Testing and calibration laboratories
ISO 15189 Medical laboratories - Particular requirements for quality and competence
OTHER REFERENCES


Australian Society for Microbiology Guidelines for Assuring Quality of Medical Microbiological Culture Media

Commonwealth of Australia, Health Insurance Act 1973, Health Insurance (Accredited Pathology Laboratories-Approval) Principles

National Health and Medical Research Council National Guidelines for Waste Management in the Health Care Industry

Clinical and Laboratory Standards Institute, Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline, 3rd Edition

Clinical and Laboratory Standards Institute, Procedures for the Collection of Diagnostic Blood Specimens by Venepuncture; Approved Standard, 4th Edition

Clinical and Laboratory Standards Institute, Procedures for the Handling and Processing of Blood Specimens; Approved Guideline, 2nd Edition

Morris EC and Fen KMK The Calibration of Weights and Balances

NATA Policy Circular No 12 NATA Accreditation Requirements for the Performance of Calibrations In-house

NSW Health Department Infection Control Policy


The Royal College of Pathologists of Australasia - Manual of Use and Interpretation of Pathology Tests

US Department of Health and Human Services, CDC and NIH Biosafety in Microbiological and Biomedical Laboratories

VIM International vocabulary of basic and general terms in metrology


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