NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR QUALITY MANAGEMENT IN MEDICAL LABORATORIES

(2007 Edition)

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Contents

National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. An ongoing function of NPAAC is to formulate standards, and initiate and promote guidelines and education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Introduction

This document is intended to supplement and to be used as a practical guide to the application of Australian Standard AS 4633:2004, Particular requirements for quality and competence. This Standard has been reproduced from, and is identical to, the International Organization for Standardization (ISO) standard ISO 15189:2003, *Medical Laboratories - Particular Requirements for Quality and Competence.* It is for use in the accreditation process, and aims to help laboratories to interpret the ISO standard, rather than to provide additional requirements. These requirements focus on all parts of Section 4 (Management requirements) of AS 4633 (ISO 15189). Requirements and guidelines for Section 5 (Technical requirements) of the standard are available in other National Pathology Accreditation Advisory Council (NPAAC) documents and the National Association of Testing Authorities, Australia (NATA) AS 4633 (ISO 15189) *Application Document - Supplementary Requirements for Accreditation in the Field of Medical Testing.*

This requirement provides the following information for each subsection of the standard:

- a cross reference to show which part of AS 4633 (ISO 15189) the requirements apply to
- a summary of the relevant ISO standard that explains the area that the standard covers, its purpose and so on
- an indication of whether the content has changed between AS 4633 (ISO 15189) and the previous standard - ISO/IEC 17025 (1999)
- information on any relevant Australian guidelines or standards
- a checklist covering each of the main points in AS 4633 (ISO 15189), and in any relevant Australian documents.

The NPAAC document *Requirements for Pathology Laboratories* (Standard 2, Quality systems) states that 'the quality system must embody the requirements International Organisation for standardisation (ISO) 15189:2003. Therefore, it is mandatory for laboratories to implement AS 4633 (ISO 15189).

Throughout this document, AS 4633:2004 (ISO 15189:2003) will be referred to as AS 4633 (ISO 15189) and ISO/IEC 17025 (1999) will be referred as ISO/IEC 17025.

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G1 Organisation and management

G1.1 Relevant section of AS 4633 (ISO 15189)

Section 4.1 of AS 4633 (ISO 15189) covers organisation and management. It explains how the laboratory should be organised and managed (including responsibilities of personnel and management) to meet the requirements of the standard.

G1.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

Where ISO/IEC 17025 referred to 'laboratory responsibility', AS 4633 (ISO 15189) specifically includes appropriate post-examination interpretation and advisory services as part of medical laboratory services.

G1.3 Supplementary information

To meet the requirements of Section 4.1.5(b), laboratories may find it useful to produce charts to indicate:

- the management and technical structure of the laboratory
- any other relationships of the laboratory with its parent organisations, hospitals, support services and government departments (e.g. using flow charts).

Further information on organisation and management can be found in the NPAAC documents *Requirements for Pathology Laboratories* (2007) and *Requirements for Supervision of Pathology Laboratories* (2006). Standard 1.2(e) of *Requirements for Supervision of Pathology Laboratories* includes information on the provision of appropriate education and continuing professional development (CPD) opportunities for scientific, technical and medical staff. CPD is the responsibility of the individual, but an organisation facilitates CPD through, for example, access to knowledge databases, conferences, seminars, workshops, and participation in research and continuing education.

G1.4 Checklist for organisation and management

The checklist below is intended as a guide only. Please refer to Section 4.1 of AS 4633 (ISO 15189) for full information on the requirements for organisation and management.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Is the laboratory identifiable?	4.1.1	☐
(b)	Is the laboratory described within a parent organisation?	4.1.1	☐
(c)	Are any off-site or satellite laboratories identifiable?	4.1.1	☐
(d)	Are all laboratory services designed to meet the needs of patients and clinical personnel responsible for patient care?	4.1.2	☐
(e)	Does the laboratory meet the relevant requirements of AS 4633 (ISO 15189) when carrying out work at its facilities?	4.1.3	☐
(f)	Are the responsibilities of laboratory personnel involved with primary samples defined?	4.1.4	☐
(g)	Does the laboratory have a documented policy on internal or external influence over testing?	4.1.4	☐
(h)	Do laboratory personnel have the appropriate authority and resources to carry out their duties?	4.1.5(a)	☐
(i)	Are laboratory personnel free from undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work?	4.1.5(b)	☐
(j)	Does the laboratory have documented policies and procedures for ensuring confidentiality?	4.1.5(c)	☐
(k)	Does the laboratory have documented policies and procedures for avoiding involvement in activities that would diminish confidence in its operation?	4.1.5(d)	☐
(l)	Is the laboratory organisation and management structure identified and documented (including responsibilities, authority and interrelationships of all personnel)?	4.1.5(e) 4.1.5(f)	☐ ☐

G1.4 Checklist for organisation and management (continued)

No.	Question	ISO ref	
(m)	Are staff given adequate training and supervision appropriate to their experience and level of responsibility, and are they given adequate opportunities for continuing professional development and is this recorded?	4.1.5(g)	☐
(n)	Does the laboratory have adequate technical management?	4.1.5(h)	☐
(o)	Does the laboratory have a designated quality manager (however named)?	4.1.5(i)	☐
(p)	Are the responsibilities and authority of the quality manager defined and documented?	4.1.5(i)	☐
(q)	Does the laboratory have deputies appointed for all key functions?	4.1.5(j)	☐
(r)	Does the laboratory comply with the NPAAC documents *Requirements for Supervision of Pathology Laboratories and Requirements for Pathology Laboratories*	NPAAC	☐

G2 Quality management system

G2.1 Relevant section of AS 4633 (ISO 15189)

Section 4.2 of AS 4633 (ISO 15189) covers the quality management system, and the means for documenting and communicating this system. It deals with:

- the minimum requirements for the system
- what a quality policy statement is and what it should cover
- a draft table of contents for a quality manual
- requirements for establishing proper calibration and function of instruments, reagents and analytical systems.

G2.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

The following changes have been made to the standards relevant to quality management systems:

- The title of Section 4.2 has changed from 'Quality system' in ISO/IEC | 17025 to 'Quality management system' in AS 4633 (ISO 15189).
- This section now requires internal quality control and participation in external quality assurance schemes to be included as part of the quality system.
- The requirements for a quality manual, which were covered in Section 4.2.2d of ISO/IEC 17025, are now covered under 4.2.4 in AS 4633 (ISO 15189). The requirement in Section 4.2.4 has been strengthened and extended (the term 'familiarise' in 4.2.2d of ISO/IEC 17025:1999 has been strengthened, and a suggested table of contents for a quality manual has been included in AS 4633:2004 (ISO 15189:2003)).
- Section 4.2.5 of AS 4633 (ISO 15189) contains a requirement to *'establish and implement a programme which regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems….'* Section 5.3.2 of the standard provides more information on this point.

G2.3 Supplementary information

Laboratory management is responsible for managing and reviewing the quality manual, and for working with the quality manager (however this position is described within the organisation). The level of detail required in the quality manual may vary between individual laboratories. If in doubt of what is required, staff should refer to their accrediting authority.

Section 4 Equipment Calibration Intervals of the NATA/AS 4633 (ISO 15189) *Application Document - Supplementary Requirements for Accreditation in the Field of Medical Testing* provides further information relevant to Section 4.2.5 and 5.3.2 of AS 4633 (ISO 15189).

Whereas AS 4633 (ISO 15189) refers to 'external quality assessment schemes', in the Australian context, this is referred to as 'external proficiency testing' in NPAAC documents.

Where the laboratory undertakes in-house IVD manufacture in accordance with NPAAC *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices* (IVDs), the laboratory should also refer to AS/ISO 13485:2003 with regard to formal quality plan requirements.

G2.4 Checklist for quality management system

The checklist below is intended as a guide only. Please refer to Section 4.2 of AS 4633 (ISO 15189) for full information on the requirements for a quality management system.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Is the quality management system documented and communicated?	4.2.1	☐
(b)	Are documented policies in place to ensure that quality management system documents are understood and implemented?	4.2.1	☐
(c)	Does the quality management system include internal quality control and participation in external proficiency testing?	4.2.2	☐
(d)	Does the laboratory have an appropriate quality policy statement?	4.2.3	☐
(e)	Does the laboratory have an appropriate quality manual?	4.2.4	☐
(f)	Are documented policies in place to ensure that all personnel are instructed on the use and application of the quality manual and associated documents?	4.2.4	☐
(g)	Are there documented processes for keeping the quality manual up to date, and which are under the authority and responsibility of an individual appointed to be responsible for quality?	4.2.4	☐
(h)	Does the laboratory have a program for monitoring and demonstrating proper calibration and function of instruments, reagents and analytical systems, and a documented and recorded program of preventive maintenance and calibration?	4.2.5	☐

G3 Document control

G3.1 Relevant section of AS 4633 (ISO 15189)

Section 4.3 of AS 4633 (ISO 15189) covers document control. It explains why document control is needed and how it should be achieved. This section also defines what is meant by a document, in terms of the standard.

G3.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

Section 4.3.1 of AS 4633 (ISO 15189) requires a defined retention period of archived copies of all documents that comprise the quality documentation.

G3.3 Supplementary information

The purpose of document control is to ensure that all critical documentation for laboratory operation is current and controlled. Effective document control ensures that any system changes in the laboratory are reflected in their documentation.

The designated person in charge of the laboratory should ensure that retention periods comply with national and jurisdictional regulations, and should define retention periods for any critical documentation, if these are not covered by national, state or local regulations. Further information on retention periods can be found in Section 4.13.3 of AS 4633 (ISO 15189).

Documents should be retained in accordance with NPAAC *Retention of Laboratory Records and Diagnostic Materials* (2002). Retention periods should be as specified in Section 4.13.3 of the NATA/AS 4633 (ISO 15189) *Application Document - Supplementary Requirements for Accreditation in the Field of Medical Testing*, where relevant.

A register of signatory records is recommended, and should be retained for the same period as any of the signed documents.

G3.4 Checklist for document control

The checklist below is intended as a guide only. Please refer to Section 4.3 of AS 4633 (ISO 15189) for full information on the requirements for document control.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have a documented procedure for document control that meets all the requirements of AS 4633 (ISO 15189)?	4.3.1	☐
(b)	Are all documents issued as part of the quality management system appropriately reviewed and approved before initial use?	4.3.2(a)	☐
(c)	Does the laboratory have a document control log (however named)?	4.3.2(b)	☐
(d)	Does the laboratory ensure that only currently authorised versions are available for active use at relevant locations?	4.3.2(c) 4.3.2(e)	☐ ☐
(e)	Does the laboratory ensure that documents are periodically reviewed and revised when necessary, and that these revisions are approved by authorised personnel?	4.3.2(d)	☐
(f)	Does the laboratory have a system to prevent the inadvertent use of documents that have been retained or archived, but have been superseded?	4.3.2(f)	☐
(g)	Does the laboratory's documentation control system allow for the amendment of documents by hand where necessary, with clear indications of how this may be done?	4.3.2(g)	☐
(h)	Does the laboratory have procedures to describe how changes to documents kept in computerised systems are to be made and controlled?	4.3.2(h)	☐
(i)	Does the laboratory ensure that all documents relevant to the quality management system are uniquely identified?	4.3.3	☐

G4 Review of contracts for medical test requests

G4.1 Relevant section of AS 4633 (ISO 15189)

Section 4.4 of AS 4633 (ISO 15189) covers review of contracts for provision of requests for medical laboratory services. It covers:

- procedures for ensuring that contracts are reviewed regularly
- what such a review should cover
- how deviations from a contract should be dealt with.

Contracts for supply of other services are covered in Section 'G6 External services and supplies'.

G4.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to review of contracts, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G4.3 Supplementary information

Review of a laboratory's ability to meet its clients' needs is an important area of the quality system. In relation to contracts and requests for medical tests, a quality system covers:

- when and in what form (verbal, paper, electronic, etc) an individual request made of a laboratory is acceptable
- documentation of any agreement on test requests between the client and the laboratory (e.g. proformas for research trials or agreed specific test profiles, abbreviations, etc) that may modify or override an individual request
- when (or at what point) a contract is entered into between the client and the laboratory to undertake the testing (if this is verbal, the quality system should include the process for detailing such requests electronically or on paper)
- the processes in place to negotiate agreed changes to a request (modifications or test add-ons, etc) and the requirement for documenting these
- the processes in place to advise a client when a test is to be referred to other laboratories, is not possible or has been rejected.

In this way, a client can be assured that requests will proceed, be referred or not proceed, and that the client will be notified of the outcome.

To comply with Australian Government Health Insurance Commission regulations allowing access to medical benefits, request forms for pathology services must meet certain requirements. The *Health Insurance Act 1973* clearly defines acceptable pathology request forms and penalties for non-compliance. Pathology request forms that are distributed to requesting practitioners must be approved by Medicare Australia where billing under Medicare is involved. The pathology section of the *Medicare Benefits Schedule*[1] provides detailed information about pathology requests.

1 See Category 6 of the schedule at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/mbsonline-downloads

G4.4 Checklist for review of contracts for medical test requests

The checklist below is intended as a guide only. Please refer to Section 4.4 of AS 4633 (ISO 15189) for full information on the requirements for review of contracts for medical test requests.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented policies and procedures for review of contracts for medical test requests?	4.4.1	☐
(b)	Are the requirements for review of contracts for medical test requests adequately defined, documented and understood?	4.4.1(a)	☐
(c)	Does the laboratory have the capability and resources to meet the contract requirements (i.e. does it have the necessary physical, personnel and information resources, and do the personnel have the necessary skills and expertise)?	4.4.1(b)	☐
(d)	Does the laboratory keep records of reviews of contracts for medical test requests?	4.4.2	☐
(e)	Do reviews of contracts include work referred by the laboratory?	4.4.3	☐
(f)	Does the laboratory have procedures to inform clients of any deviation from a contract for medical test requests?	4.4.4	☐
(g)	Are reviews of contracts for medical test requests repeated if contracts are amended after work has commenced?	4.4.5	☐
(h)	Are request forms held for the time specified by NPAAC standards and guidelines?	NPAAC	☐

G5 Examination by referral laboratories

G5.1 Relevant section of AS 4633 (ISO 15189)

Section 4.5 of AS 4633 (ISO 15189) covers examination by referral laboratories. It deals with:

- evaluating and selecting referral laboratories and consultants
- reviewing arrangements with, and keeping records of, referral laboratories
- the responsibilities of referring and the referral laboratories in providing results.

G5.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

Whereas ISO/IEC 17025 required laboratories to ensure that subcontracted work was placed with a competent subcontractor, AS 4633 (ISO 15189) requires the laboratory to have an effective documented procedure for evaluating and selecting referral laboratories. Section 4.5.1 has been expanded to cover not just referral laboratories, but also the consultants who are to provide second opinions for histopathology, cytology and related disciplines. This section of the revised standard also explains that the referring laboratory is responsible for ensuring that the referral consultant is competent to perform the requested examinations.

In addition, Section 4.5.4 of AS 4633 (ISO 15189) more clearly defines the responsibility for reporting results.

G5.3 Supplementary information

A competent referral laboratory is described by the National Association of Testing Authorities, Australia (NATA) as one accredited by NATA or one of NATA's mutual recognition partners for the testing concerned. This definition may be utilised as the laboratory's documented procedure for evaluation and selection of referral laboratories.

The accreditation status of referral laboratories must be reviewed regularly to ensure currency with records kept. The simplest means of doing this is to periodically obtain a copy of the referral laboratory's scope of accreditation from the NATA website at www.nata.asn.au.

Where a referral laboratory is not accredited, the referring laboratory needs to have a process for evaluating the competence of that laboratory by other means (e.g. publications, professional reputation).

The referring laboratory will not be held responsible for tests sent to a laboratory at the specific request of a requesting practitioner if that laboratory is not one included on the referring laboratory's list of accepted or usual referral laboratories or does not meet the standards normally expected.

G5.4 Checklist for examination by referral laboratories

The checklist below is intended as a guide only. Please refer to Section 4.5 of AS 4633 (ISO 15189) for full information on the requirements for examination by referral laboratories.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented policies for evaluating and selecting referral laboratories and/or consultants (including accreditation and performance criteria)?	4.5.1	☐
(b)	Does the laboratory have a system for reviewing arrangements with referral laboratories to ensure that: • requirements are adequately defined, documented and understood • the laboratory can meet requirements • there are no conflicts of interest • examination procedures are appropriate • responsibilities for interpretation of results are clearly defined?	4.5.2	☐
(c)	Does the laboratory keep records of reviews of arrangements with referral laboratories?	4.5.2	☐
(d)	Does the laboratory keep a register of all referral laboratories that it uses?	4.5.3	☐
(e)	Does the laboratory keep a register of all samples that have been referred to another laboratory?	4.5.3	☐
(f)	Are users of laboratory services given the name and address of the laboratory responsible for examination reports?	4.5.3	☐
(g)	Are duplicates of laboratory reports retained in the permanent file of the laboratory and provided to the referring practitioner for retention in the patient file?	4.5.3	☐
(h)	Does the laboratory ensure that referral laboratory examinations and findings are provided to the person making the request?	4.5.4	☐
(i)	Are the quality and performance of referral laboratories monitored?	NPAAC	☐

G6 External services and supplies

G6.1 Relevant section of AS 4633 (ISO 15189)

Section 4.6 of AS 4633 (ISO 15189) covers the acquisition of external supplies and services. It deals with:

- selection and use of purchased external services, equipment and consumable supplies
- verifying compliance with standard specifications or requirements
- an inventory control system for supplies
- evaluation of suppliers.

G6.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In AS 4633 (ISO 15189), Section 4.6.3 has been expanded to include a requirement for an inventory control system for supplies, which specifies minimum records to be kept and the availability for laboratory management review.

G6.3 Supplementary information

The quality of the products and services produced and provided begins with the materials and services the laboratory procures. AS 4633 (ISO 15189) does not cover the fiscal arrangements the organisation may have for external services and supplies.

G6.4 Checklist for external services and supplies

The checklist below is intended as a guide only. Please refer to Section 4.6 of AS 4633 (ISO 15189) for full information on the requirements for external services and supplies.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented policies and procedures for the selection and use of external services, equipment and consumable supplies that affect the quality of its service?	4.6.1	☐
(b)	Where purchased items consistently fail to meet the laboratory's quality requirements, is appropriate action taken?	4.6.1	☐
(c)	Does the laboratory have documented procedures for inspection, acceptance or rejection, and storage of purchased products and services?	4.6.1	☐
(d)	Are supplies checked for compliance with requirements before use and are records kept?	4.6.2	☐
(e)	Does the laboratory have an inventory control system for supplies?	4.6.3	☐
(f)	Does the laboratory keep appropriate quality records of external services, supplies and purchased products?	4.6.3	☐
(g)	Does the laboratory evaluate suppliers of critical reagents, supplies and services that affect the quality of its service?	4.6.4	☐
(h)	Are supplier evaluations recorded, and does the laboratory keep a list of approved suppliers?	4.6.4	☐

G7 Advisory services

G7.1 Relevant section of AS 4633 (ISO 15189)

Section 4.7 of AS 4633 (ISO 15189) covers advisory services. It looks at the provision and documentation of professional advice to clients on choice of examination and use of services.

G7.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

Section 4.7 of AS 4633 (ISO 15189) is new; it has no equivalent in ISO 17025.

G7.3 Supplementary information

Standard 2 of the NPAAC document *Requirements for Supervision of Pathology Laboratories* (2006) contains further information on advisory services (consultation).

AS 4633 (ISO 15189) encourages regular documented meetings between professional and clinical staff, as well as participation in clinical rounds.

Section 5.5.6 of AS 4633 (ISO 15189) requires the laboratory to make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to laboratory users on request.

G7.4 Checklist for advisory services

The checklist below is intended as a guide only. Please refer to Section 4.7 of AS 4633 (ISO 15189) for full information on the requirements for advisory services.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Do appropriate laboratory professional staff provide advice on choice of examinations and use of services?	4.7	☐
(b)	Where applicable, are there documented meetings of professional staff with clinical staff regarding use of laboratory services?	4.7	☐
(c)	Where applicable, are there documented meetings of professional staff with clinical staff for the purpose of consultation on scientific matters?	4.7	☐
(d)	Where applicable, do professional staff participate in clinical rounds?	4.7	☐

G8 Resolution of complaints

G8.1 Relevant section of AS 4633 (ISO 15189)

Section 4.8 of AS 4633 (ISO 15189) covers the resolution of complaints.

G8.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

Regarding resolution of complaints, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G8.3 Supplementary information

The laboratory requires a documented policy for recording and dealing with complaints. This includes those arising from requesting doctors, patients, suppliers (external 'customers') and laboratory staff (internal 'customers'). Incidents, suggestions or observations of non-compliance may be considered in this category. These lead logically into corrective action if assessed as appropriate.

G8.4 Checklist for resolution of complaints

The checklist below is intended as a guide only. Please refer to Section 4.8 of AS 4633 (ISO 15189) for full information on the requirements for resolution of complaints.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented policies and procedures for resolving complaints and other feedback from clinicians, patients or other parties?	4.8	☐
(b)	Is there a mechanism for investigating complaints or adverse incidents?	4.8	☐
(c)	Are complaints, investigations and corrective actions recorded, and do they lead to corrective action and review by senior management?	4.8	☐

G9 Identification and control of nonconformities

G9.1 Relevant section of AS 4633 (ISO 15189)

Section 4.9 of AS 4633 (ISO 15189) covers the identification and control of nonconformities. It deals with:

- responsibilities for detecting and correcting any aspects of examinations that do not conform to requirements
- eliminating the causes of non-compliance
- dealing with results in the case of non-compliance.

G9.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

The requirements for dealing with nonconformities have been strengthened in AS 4633 (ISO 15189).

G9.3 Supplementary information

Any variation from the normal or accepted process, procedure or protocol should be considered a nonconformance. This includes any errors in test results discovered by quality control processes, or by regular audits of laboratory procedures. In terms of the quality system, a nonconformance can occur only if there is a variation from stated quality system information in the quality manual. Similarly, operational nonconformance can result from any other documented procedure, process or protocol.

G9.4 Checklist for identification and control of nonconformities

The checklist below is intended as a guide only. Please refer to Section 4.9 of AS 4633 (ISO 15189) for full information on the requirements for identification and control of nonconformities.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented policies and procedures to be implemented when it detects nonconformities?	4.9.1	☐
(b)	Does the laboratory have designated personnel responsible for problem resolution, and defined actions to be taken?	4.9.1(a)	☐
		4.9.1(b)	☐
(c)	Are complaints, investigations and corrective actions recorded, and do they lead to corrective action and review by senior management?	4.8	☐
	In the event that nonconformity is detected, are there procedures for:	4.9.1(c)	☐
		4.9.1(f)	☐
	• considering the medical significance and informing the requesting clinician, where appropriate		
	• halting examinations and withholding reports		
	• immediate correction of the nonconformity		
	• recalling or identifying released results of nonconforming examinations?		
(d)	Does the laboratory specify who is responsible for authorising resumption of examinations?	4.9.1(g)	☐
(e)	Does the laboratory have procedures for documenting and recording each episode of nonconformity, and are these records regularly reviewed to detect trends and initiate preventive action?	4.9.1(h)	☐
(f)	Does the laboratory have procedures for identifying, documenting and eliminating the cause of nonconforming examinations?	4.9.2	☐
(g)	Does the laboratory define and implement procedures for recording, releasing and reviewing results in the case of nonconformities?	4.9.3	☐

G10 Corrective action

G10.1 Relevant section of AS 4633 (ISO 15189)

Section 4.11 of AS 4633 (ISO 15189) covers corrective action. It deals with:

- determining the underlying cause of any problems
- documenting changes made as a result of investigations into corrective actions
- monitoring the effectiveness of corrective actions
- auditing where an investigation suggests that there is non-compliance.

Trends in corrective action requests are covered in Section G15 (Management review).

G10.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to corrective action, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G10.3 Supplementary information

The aim of this element is to ensure that laboratories have effective mechanisms for identifying and investigating actual or potential problems with product quality or breakdowns in the quality system, and for using such situations to improve the system and its processes.

Failures in the quality of test results are an obvious area for corrective actions. However, such actions may also be required when problems in the quality system are identified through processes such as reviews, audits and complaints.

Where situations have an immediate impact upon patient care and treatment, immediate corrective actions are needed. Such incidents also require a process or procedure that defines which personnel are authorised to take immediate corrective action and the mechanism for recording the incident.

Investigations to establish corrective actions need to be wide ranging and should analyse all possible causes. To allow for a complete analysis of the process, a particular test may be chosen and followed completely from request and collection to receipt of results by the requesting medical officer. This type of process may cover many sections of a laboratory.

Feedback on corrective action taken in response to a complaint is considered good customer service. Management should:

- select the action most likely to eliminate the problem and prevent recurrence
- approve the implementation of corrective actions
- ensure amendments are made to documentation
- establish a review process to monitor the success or otherwise of the corrective actions.

A typical format for a corrective action request is shown below.

Where the laboratory undertakes in-house IVD manufacture in accordance with NPAAC *Requirements for the Development and use of In-house In Vitro Diagnostic Devices* (IVDs) the laboratory should also refer to AS/ISO 13485:2003 (Medical devices - Quality management systems - requirements for regulatory purposes) with regard to the need to perform risk assessment at critical failure points in the manufacturing process.

G10.4 Typical format for a corrective action request

Corrective action request (CAR) No.

☐ QC/QAP ☐ Audit ☐ Complaint/suggestion ☐ Other

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1. Description of nonconformance

Reported by | Date | Copy sent to QM

Yes ☐ No ☐

Assigned to | For action by

---

2. Action taken to correct nonconformance (immediate fix)

Reported by | Date | Copy sent to QM

Yes ☐ No ☐

---

3. Action required on underlying cause (corrective action)

Reported by | Date | Copy sent to QM

Yes ☐ No ☐

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4. If yes to 3: corrective action taken

Reported by | Date | Copy sent to QM

Yes ☐ No ☐

Approved

Quality manager | Date

G10.5 Checklist for corrective action

The checklist below is intended as a guide only. Please refer to Section 4.10 of AS 4633 (ISO 15189) for full information on the requirements for corrective action.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No	Question	ISO ref	
(a)	Does the laboratory have documented procedures for corrective action?	4.10.1	☐
(b)	Are changes resulting from investigations of corrective actions documented and implemented?	4.10.2	☐
(c)	Does the laboratory have procedures for monitoring the results of corrective actions, to ensure that they have been effective?	4.10.3	☐
(d)	Does the laboratory audit and review policies, procedures and protocols where investigations of corrective actions have cast doubt on compliance?	4.10.4	☐

G11 Preventive action

G11.1 Relevant section of AS 4633 (ISO 15189)

Section 4.11 of AS 4633 (ISO 15189) covers preventive action. It deals with:

- identifying where preventive action is needed
- determining what actions should be taken.

G11.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to preventive action, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G11.3 Supplementary information

Preventive action is needed to ensure that a laboratory has effective mechanisms or systems for:

- capturing ideas and identifying material that can lead to improvements
- identifying areas that have the potential to cause problems (i.e. risk assessment).

Laboratories can achieve this by, for example, analysing trends, proficiency testing data and customer surveys; and by carrying out reviews and risk assessments.

Laboratories should be committed to taking preventive action or implementing quality improvements as opportunities present. Such action should not be seen as response to nonconformance, but as a proactive mechanism to implement improvements before nonconformance occurs.

Feedback to groups or individuals who may be affected by changes due to the implementation of preventive action helps to provide customers with evidence of quality improvements within the laboratory.

Where the laboratory undertakes in-house IVD manufacture in accordance with NPAAC *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices* (IVDs), the laboratory should also refer to AS/ISO 13485:2003 with regard the need to perform risk assessment for manufacture and distribution of IVDs (assay materials, including media and reagents) between laboratories within the one network.

G11.4 Checklist for preventive action

The checklist below is intended as a guide only. Please refer to Section 4.11 of AS 4633 (ISO 15189) for full information on the requirements for preventive action.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have documented procedures for preventive action?	4.11.1	☐
(b)	Does the laboratory undertake risk assessment?	4.11.1	☐
(c)	Where preventive actions are required, does the laboratory develop, implement and monitor action plans?	4.11.1	☐
(d)	Is there a process of data collection, analysis and review that may lead to preventive actions?	4.11.2	☐

G12 Continual improvement

G12.1 Relevant section of AS 4633 (ISO 15189)

Section 4.12 of AS 4633 (ISO 15189) covers continual improvement. It deals with:

- establishing procedures for ensuring that continual improvement occurs
- evaluating actions
- implementing changes
- providing educational and training opportunities.

G12.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In contrast to ISO/IEC 17025, AS 4633 (ISO 15189) separates opportunities for improvement from preventive action, and includes a section about continual improvement. Section 4.12 of AS 4633 (ISO 15189) requires laboratories to:

- implement a regular systematic review of all operational procedures by laboratory management, from which action plans for improvement can be developed (Section 4.12.1)
- evaluate the effectiveness of action taken through focused review or audit (Section 4.12.2)
- review and implement changes to quality systems resulting from outcomes of action taken following the review (Section 4.12.3)
- develop quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (Section 4.12.4)
- provide educational and training opportunities, not only for laboratory personnel, but also for relevant users of laboratory services (Section 4.12.5).

G12.3 Supplementary information

Continual improvement is the mechanism by which an organisation continually improves its services through audit, corrective actions, preventive actions, addressing particular questions (focused review), risk assessment and review of critical events.

The quality system should document the education and continuing professional development (CPD) requirements for staff, as set out in the NPAAC document *Requirements for Supervision of Pathology Laboratories.* CPD of all staff especially scientific staff, managers and medical staff is considered a fundamental requirement of their role. Documentation of professional development, or participation in CPD programs relevant to their profession, is encouraged where this is not mandatory.

CPD remains the responsibility of the individual. However, the organisation should facilitate this through access to knowledge databases, conferences, seminars, workshops, participation in research, etc.

G12.4 Checklist for continual improvement

The checklist below is intended as a guide only. Please refer to Section 4.12 of AS 4633 (ISO 15189) for full information on the requirements for continual improvement.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have a procedure for regular systematic review of all operational procedures?	4.12.1	☐
(b)	Are action plans for improvement developed, documented and implemented, as appropriate?	4.12.1	☐
(c)	Does the laboratory have procedures for evaluating actions taken as a result of review of operational procedures?	4.12.2	☐
(d)	Does the laboratory review the quality management system if required?	4.12.2	☐
(e)	Does the laboratory management review and implement changes to the quality management system resulting from actions taken as a result of review of operational procedures?	4.12.3	☐
(f)	Does the laboratory implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care?	4.12.4	☐
(g)	Does the laboratory address opportunities for improvement identified by the program for monitoring and evaluation?	4.12.4	☐
(h)	Does the laboratory participate in quality improvement activities that deal with relevant areas and outcomes of patient care (e.g. clinical indicators of the Australian Council of Healthcare Standards)?	4.12.4	☐
(i)	Does the laboratory provide access to suitable educational and training opportunities for all laboratory personnel and relevant users of laboratory services?	4.12.5	☐

G13 Quality and technical records

G13.1 Relevant section of AS 4633 (ISO 15189)

Section 4.13 of AS 4633 (ISO 15189) covers quality and technical records. It deals with:

- establishing and implementing such records
- methods for storage
- duration of storage.

This section also defines records, in terms of the standard.

G13.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to quality and technical records, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G13.3 Supplementary information

The intent of this element is to ensure that all laboratory records are maintained according to their relevance to the laboratory's operations. This will include all management and technical records with respect to identification, collection, filing, storage access and disposal.

Records should be kept in accordance with NPAAC publication *Retention of Laboratory Records and Diagnostic Material* (2002), and relevant Medicare Australia (MA) regulations. Section G3 (Document control) contains further information on retention of documents.

Records (including electronic records) relating to tests and calibrations must contain the identity of the personnel responsible for performing those tasks. Records may be retained in electronic form. Section 4.13 of the NATA/AS 4633 (ISO 15189) Application document provides further information relevant to the subject.

Any records containing errors must not be made illegible in any way. Mistakes may be crossed out and any alteration or change should be initialled and dated. A register of signatory records is recommended and should be retained for the same period as the documents.

G13.4 Checklist for quality and technical records

The checklist below is intended as a guide only. Please refer to Section 4.13 of AS 4633 (ISO 15189) for full information on the requirements for quality and technical records.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory have procedures for identifying, collecting, indexing, accessing, storing, maintaining and safely disposing of quality and technical records?	4.13.1	☐
(b)	Are all records legible and readily retrievable from storage?	4.13.2	☐
(c)	Does the laboratory's record storage system meet NPAAC and MA requirements?	NPAAC	☐
(d)	Does the laboratory have a policy defining the length of time records are to be retained?	4.13.3	☐
(e)	Is the range of records kept comprehensive?	4.13.3	☐
(f)	Do staff sign, date (where appropriate) and record their identity (including electronic signatures) on all test-related documents?	NPAAC	☐
(g)	Does the laboratory have a register of signatory records?	NPAAC	☐

G14 Internal audits

G14.1 Relevant section of AS 4633 (ISO 15189)

Section 4.14 of AS 4633 (ISO 15189) covers internal audits. It deals with:

- the need for internal audits
- the process for carrying out and reviewing the results of such audits.

G14.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to internal audits, AS 4633 (ISO 15189) does not differ significantly from ISO/IEC 17025.

G14.3 Supplementary information

This element requires a laboratory to conduct internal audits of its activities to ensure continued compliance with its quality system and the requirements of AS 4633 (ISO 15189).

Effective internal audits will:

- provide assurance to management that the quality system is being implemented as intended
- help to identify the causes of quality problems and breakdowns in the quality system, and to determine the corrective action needed to eliminate them
- highlight opportunities for improving the efficiency and effectiveness of the quality system as a whole.

One possible approach to carrying out an internal audit is outlined below.

G14.3.1 Audit schedule

An audit schedule could be drawn up as a matrix, covering six months or a year, in which dates are set for auditing each part of the quality system and associated laboratory operations. Critical processes should be identified and given most attention. The quality manager is responsible for planning and organising audits as required by the schedule, requested by management or in response to previously identified nonconformance. A typical format for an audit schedule is shown below.

Audit schedule for 2005												
Month	J	F	M	A	M	J	J	A	S	O	N	D
Activity to audit												
Accommodation	x											
Staff Training		x										
Equipment			x									
Records				x								
Etc												

G14.3.2 Auditors

Audits must be conducted by trained and qualified staff who are, wherever resources permit, independent of the activity being audited; the laboratory should keep a register of trained auditors. The audit program should involve as many staff as possible, each being given a particular area of audit responsibility. Ideally, auditors should possess the appropriate personal attributes (i.e. diplomacy, impartiality) and communication skills, a suitable technical background and some understanding of quality management.

G14.3.3 Audit checklist

The use of a prepared checklist saves time during the audit and helps to prepare the auditor. Checklists should cover all the elements of AS 4633 (ISO 15189) (systems audit) or all steps in the procedure documentation (compliance audit). Such procedure documentation may include the quality manual, methods manuals, equipment maintenance schedules, etc. Initially, the laboratory audits should focus on establishing that all elements of AS 4633 (ISO 15189) have been addressed satisfactorily. The next progression is organising a number of audits based on checking that the laboratory is actually doing what it says it's doing (i.e. whether procedures in practice are consistent with the documented procedures).

A typical checklist format is shown below.

Audit checklist			
Procedure ref	**Requirement**	**Compliance**	**Comment or ref**

G14.3.4 Audit report

After the auditor has worked systematically through the checklist, the findings are discussed with the audited laboratory management and agreement reached on the completion date for corrective action to be taken on any non-compliances raised. Such details constitute the audit report, which officially lists the corrective action requests (CARs - see guideline on corrective actions, above) raised by the audit. Audit reports also present opportunities to reinforce good areas of laboratory practice and need not necessarily only represent those areas that require action
for non-compliance.

A typical audit report format is shown below.

Audit report						
Audit No.	**Activity/ procedure audited**	**Auditor**	**Planned date**	**Date performed**	**CARs raised**	**CARs closed out**

A corrective action register, cross-referenced to specific CARs, may be useful as a method of reviewing/monitoring the outcome of audits, particularly as part of the management review process.

A complete set of audit records (i.e. checklists of activities audited, CARs and reports) should be retained by the quality manager.

Support from the highest level of management is essential for the internal audit program to be carried out with success.

G14.4 Checklist for internal audits

The checklist below is intended as a guide only. Please refer to Section 4.14 of AS 4633 (ISO 15189) for full information on the requirements for internal audits.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does the laboratory's quality system define how often internal audits should be carried out?	4.14.1	☐
(b)	Do audits include all aspects of the laboratory quality system and operation (managerial and technical)?	4.14.1	☐
(c)	Do internal audits emphasise areas critical to patient care?	4.14.1	☐
(d)	Are internal audits planned, organised and carried out by the quality manager (or designated qualified personnel) to ensure that personnel do not audit their own activities?	4.14.2	☐
(e)	Are procedures for internal audits defined and documented?	4.14.2	☐
(f)	When deficiencies or opportunities for improvement are identified by an internal audit, does the laboratory undertake and document appropriate corrective or preventive actions within an agreed timescale?	4.14.2	☐
(g)	Are the main elements of the quality system audited internally about every 12 months?	4.14.2	☐
(h)	Does laboratory management review the results of internal audits?	4.14.3	☐

G15 Management review

G15.1 Relevant section of AS 4633 (ISO 15189)

Section 4.15 of AS 4633 (ISO 15189) covers management review. It deals with:

- the need for such review
- how the results should be used
- how frequently management review should occur and what it should involve.

G15.2 Differences between AS 4633 (ISO 15189) and ISO/IEC 17025

In relation to management review, AS 4633 (ISO 15189) differs on some points from ISO/IEC 17025; in particular, the standard refers specifically to:

- post-examination professional advisory activities (Section 4.15.1)
- monitoring turnaround times (Section 4.15.2)
- the need to objectively monitor and evaluate the quality and appropriateness of the laboratory's contribution to patient care (Section 4.15.3).

G15.3 Supplementary information

This element requires a laboratory's highest level of management to conduct a periodic review of the quality system and associated operations, to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. Since it is the highest level of management that defines the laboratory's objectives for quality, it is this group of 'change-agents' that should continually review the effectiveness of the system. Management review ensures that laboratory management 'step back' and look at the performance of the service over a period of time.

Part of the review process is to look at trends and patterns in corrective and preventive action, and in internal audits, to assess the need for action.

G15.4 Checklist for management review

The checklist below is intended as a guide only. Please refer to Section 4.15 of AS 4633 (ISO 15189) for full information on the requirements for management review.

If the answer to any of the questions in the checklist below is 'no', the laboratory will need to provide an explanation of why this is the case.

No.	Question	ISO ref	
(a)	Does laboratory management regularly review the quality management system?	4.15.1	☐
(b)	Does laboratory management regularly review preventive actions?	4.15.1	☐
(c)	Are the results of the review incorporated into an action plan?	4.15.1	☐
(d)	Does laboratory management regularly review internal audits?	4.15.1	☐
(e)	Are procedures for internal audits defined and documented?	4.15.1	☐
(f)	Does the review take account of the full range of issues listed in the standard?	4.15.2	☐
(g)	Are the quality and appropriateness of the laboratory's contribution to patient care (e.g. turnaround times) monitored and evaluated objectively?	4.15.3	☐
(h)	Are findings and actions arising from management reviews documented and communicated to laboratory staff?	4.15.4	☐
(i)	Are action plans and the actions associated with them, arising from management reviews, implemented within an appropriate time?	4.15.4	☐

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