NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS QUALITY CONTROL, EXTERNAL QUALITY ASSURANCE AND METHOD EVALUATION

(Sixth Edition 2018)

NPAAC Tier 3B Document

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Australian Government Department of Health

Contents

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. A function of NPAAC is to formulate Standards and initiate and promote 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.

Scope

The *Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018)* is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services* (RMPS). The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

The RMPS requires that the laboratory must have a documented and monitored Quality System in place that addresses issues such as:

- Quality Control, Internal Quality Assurance and External Quality Assurance processes
- validated and/or verified recognised procedures that must be used, if available
- aligning analytical performance of methods to meet the requirements for clinical application of the test results.

The *Requirements for Quality Control, External Quality Assurance and Method Evaluation* outlines the general features that an IQC system and an EQA program must have to provide an effective monitoring strategy for the various pathology disciplines. This document also provides guidance on method evaluation for laboratories.

Abbreviations

Abbreviation	Description
AS	Australian Standard
CLSI	Clinical Laboratory and Standards Institute
EQA	External Quality Assurance
IQA	Internal Quality Assurance
IQC	Internal Quality Control
ISO	International Organization for Standardization
KPI	Key Performance Indicator
NATA	National Association of Testing Authorities, Australia
NPAAC	National Pathology Accreditation Advisory Council
OECD	Organisation for Economic Cooperation and Development
QA	Quality Assurance
QC	Quality Control
RMPS	Requirements for Medical Pathology Services
SD	Standard Deviation

Definitions

Term	Definition
Accuracy (of measurement)	means closeness of the agreement between the result of a measurement and the true value of the measurand.
Bias	means the systematic error of the measuring instrument.
Control Material	means a device, solution, or lyophilised preparation intended for use in the Quality Control process to monitor the reliability of a test system and to maintain its performance within established limits, or means a material to be used for the assessment of the performance of an analytical procedure or part thereof.
Designated Person	means the same as the definition in the *Requirements for Medical Pathology Services.*
External Quality Assurance (EQA)	means a program in which multiple specimens are periodically sent to laboratories for analysis and/or identification, in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others. Such a program may also compare an individual's results with those of their peer group.
Imprecision	means the dispersion of independent results of measurements obtained under specified conditions. Imprecision is expressed numerically as standard deviation or coefficient of variation.[*] *Note: The term 'imprecision' is used rather than 'precision' because the common measures used, such as standard deviation and coefficient of variation, are measures of imprecision.*

[*] Clinical and Laboratory Sciences Institute Harmonized Terminology Database

Term	Definition
In house IVD	means the same as the definition in the *Therapeutic Goods (Medical Devices) Regulations 2002.* This is an IVD medical device that is: (a) within the confines or scope of an Australian laboratory or Australian laboratory network (i) developed from first principles, or (ii) developed or modified from a published source, or (iii) developed or modified from any other source, or (iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and (b) not supplied for use outside that laboratory or laboratory network.
Internal Quality Control (IQC)	means operational techniques and activities at the point of use that are used to fulfil requirements for the quality of Medical Pathology Services.
Internal Quality Assurance (IQA)	means activities that aim to help monitor performance, drive improvement and support collaborative on-going professional practice. For example, activities that: • improve the quality of patient management and/or outcomes • focus on peer-review and technical audit • require documented evidence of a pathologist's involvement • are practice based and developed in consultation with discipline advisory committees.
Interpretative Tests	means tests where the result is based on pattern recognition using the interpretative expertise of an appropriately qualified and experienced scientist or pathologist (for example, most histopathology and cytology tests, many microbiology tests and morphological haematology).
Measurement Error	means the result of a measurement minus the true value of the measurand.
Measurand	means the quantity intended to be measured.
Measurement Uncertainty	means a parameter associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand.
Method validation	means the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with what the application requires.
Method verification	means procedures to test what extent the performance data obtained by manufacturers during method validation can be reproduced in the environments of end-users.

Term	Definition
Precision	means closeness of agreement between independent test results from the same specimen obtained under stipulated conditions.
Qualitative Tests	means tests where there may only be two outcomes (positive/negative; detected/not detected) or where the degree of change in the test procedure is ranked on a relative or semi-quantitative scale (e.g. 1+, 2+, 3+ as for urine drugs of abuse screening, pregnancy tests).
Quality	means the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.
Quality Assurance (QA)	means part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality Control (QC)	means operational techniques and activities that are used to fulfil requirements for quality.
Quantitative tests	means tests whose output can be measured on a metric scale (for example, most clinical biochemistry tests and many haematological measurements).
Requirements for Medical Pathology Services (RMPS)	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily meeting demands/requirements in a timely manner.

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Introduction

The *Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018)* is a Tier 3B document. It is issued by the National Pathology Accreditation Advisory Council (NPAAC) to guide laboratories in Australia about the minimum standards considered acceptable when participating in quality control, external quality assurance programs and method evaluation.

Effective quality control procedures ensure that tests and procedures fall within defined quality specifications. Failure of quality control can potentially cause risks to patients. The designated person is therefore responsible for the oversight of the process. Where clinically important QC failures occur, it is imperative that the release of results is suspended and the cause of the failure is identified and rectified. All affected results must be retracted and re-assayed.

To ensure patient safety, all methods in use should undergo validation/verification to demonstrate fitness for their intended purpose. Method validation and verification provide objective evidence that a method meets the performance requirements suitable for its intended use. Therefore, all in-house assays and modified standard methods must undergo validation and all commercial assays must have their performance verified *in situ*.

External assessments of diagnostic laboratories have frequently identified failures in quality control procedures, misinterpretation of EQA results and inadequate method evaluation to be common and important areas of risk. Satisfactory participation in EQA is a requirement for all pathology laboratories seeking accreditation. EQA testing programs must be available in order to establish standards of acceptability. EQA programs are used in all disciplines and for all categories of pathology tests to assess performance and are most effective when the assessments can be compared with the performance of peers. EQA schemes compare testing outcomes of different laboratories with target or consensus values.

These Requirements have been developed with reference to Australian regulations and standards from the International Organization for Standardization, including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence.*

The Requirements should be read within the national pathology accreditation framework in conjunction with the current version of the following NPAAC documents:

All Tier 2 and 3 Documents.

In addition to these Standards, laboratories must comply with all relevant state and territory legislation (including any reporting requirements).

In each section of the present document, points deemed important for practice are identified as either ‘Standards’ or ‘Commentaries’.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a laboratory can attain accreditation – Standards are printed in bold type and prefaced with an ‘S’ (e.g. **S2.2)**. The use of the word **‘must’** in each Standard indicates a mandatory requirement for pathology practice.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context, whether they are associated with a Standard or not. Note that when Commentaries expand on a Standard or refer to other legislation, they assume the same status and importance as the Standards or legislation to which they are attached. Where a Commentary contains the word **'must'** then that commentary is considered to be **normative**.

Please note that all NPAAC documents can be accessed at Department of Health

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Assuring Quality in Patient Results

(Refer to Standard 3, Standard 4 and Standard 8 in *Requirements for Medical Pathology Services*)

Quantitative results are reported numerically and are compared with an accompanying reference interval for interpretation. Therefore, it is important for a laboratory to be confident that these results are fit for purpose and as accurate and precise as possible. This assurance is gained by using an appropriate QC system that comprises both internal QC and EQA procedures.

The goal of the QC/EQA process is to minimise the potential risk of issuing erroneous results that may lead to patient harm, and to improve the overall performance of the pathology service. Performance goals are to:

- determine if specific assays and procedures are fit for purpose
- document who has responsibility for improving poorly performing assays and procedures
- guide the setting of the target performance of qualitative and quantitative assays and procedures, and
- determine the significance of a QC/EQA failure e.g. the impact on patient results.

S1.1 The designated person is responsible for the selection and documentation of performance goals for all laboratory assays and procedures.

C1.1(i) Documentation **must** include the:

(a) selection of assays and procedures that are fit for purpose

(b) selection of targets and ranges for QC samples

(c) acceptance criteria for QC results.

C1.1(ii) Performance goals should be set with consideration given to the measurand, procedure and the clinical situation.

2. Quality Control

(Refer to Standard 5 and Standard 8B in *Requirements for Medical Pathology Services*)

S2.1 The designated person must ensure that every laboratory assay has a documented QC process that assesses the performance of the test.

C2.1(i) QC materials **must** have concentrations that are clinically relevant and within the boundaries of their method's measurement range.

C2.1(ii) For quantitative assays, target values and SDs **must** be determined using laboratory data.

C2.1(iii) For qualitative assays, QC processes **must** confirm the test is performing as intended.

C2.1(iv) Frequency of QC samples in an analytical run **must** be appropriate for each assay.

S2.2 The designated person must have a documented escalation procedure for all staff to follow if there has been a QC failure.

C2.2 This **must** include a procedure for evaluating any patient specimens that were measured between the last successful QC sample and the first failed QC sample.

3. Internal Quality Assurance

(Refer to Standard 3, Standard 5A and Standard 8 in *Requirements for Medical Pathology Services*)

It is mandatory that all pathologists or scientists involved in making diagnoses are involved in IQA/QC and EQA (refer to Standard 5) activities pertinent to their diagnostic activities. These areas of pathology include Anatomical Pathology, Cytology, Morphological Haematology, Cytogenetics, Chemical and to a lesser degree, Immunology and Microbiology.

S3.1 The designated person must ensure all pathologists and scientists involved in making morphological diagnoses participate in IQA activities relevant to their practice.

C3.1 Activities include analysis of pre-analytic (laboratory sample preparation), analytic (diagnostic) and post-analytic (report integrity and delivery) steps.

S3.2 All pathologists must participate in diagnostic peer review activities as a component of IQA.

C3.2(i) Records of peer-review diagnostic activities **must** be kept.

C3.2(ii) The laboratory **must** have clearly documented procedures detailing which, if any, diagnostic specimen types or diagnoses are subject to mandatory peer review, and the procedures to be followed in the event of discordance of diagnosis.

C3.2(iii) Peer-review includes comparison of diagnoses, whether through formal sample exchange, formal second opinion or informal second opinion. Both pathologists involved in the exchange of diagnostic opinions are regarded as being involved in the peer-review process.

4. Pre and Post-Analytical Quality Assurance

(Refer to Standard 5, and Standard 8A and 8B in *Requirements for Medical Pathology Services*)

Pre- and post-analytical factors are not always under the control of laboratories, but are known to affect patient safety.

S4.1 Laboratories must have documented QA procedures to ameliorate any potential risks to patient safety associated with pre-and post-analytical factors.

C4.1(i) Documented procedures **must** be in place for the QA of the pre- and post-analytical phases.

C4.1(ii) The frequency of QA activities by a designated person **must** be based on the potential risks to patient safety.

S4.2 Laboratories must identify high risk areas and compare their data with other accredited laboratories to ensure they demonstrate acceptable performance.

C4.2 Laboratories should be enrolled in an EQA program covering the pre-and post-analytical phases, where available.

5. Enrolment and Participation in External Quality Assurance Programs

(Refer to Standard 5 and Standard 8 in *Requirements for Medical Pathology Services*)

The results of EQA programs need to be evaluated in the context of risk to patients and patient care.

S5.1 The designated person must be responsible for the enrolment, participation, assessment and confirmation of satisfactory performance of the laboratory and individual staff in relevant EQA programs.

C5.1(i) The enrolment, participation and evaluation **must** be documented.

C5.1(ii) The laboratory **must** participate in a relevant quality assurance program for each test or, where relevant, group of tests, if available.

C5.1(iii) Processing and reporting of EQA materials **must** be performed in a similar manner to processing and reporting analysis of routine specimens received in the laboratory, wherever possible.

S5.2 The designated person must document the acceptable performance criteria together with the steps for escalation in response to any EQA failures and the process for resolution of any issues.

C5.2(i) The EQA **must** be reviewed and non-concordant results and failures **must** be investigated in a timely manner and appropriate actions taken and documented.

C5.2(ii) The potential risk posed to patients from the failure of the test procedure **must** be considered.

C5.2(iii) The designated person **must** be informed of any significant failures at the earliest possible time.

S5.3 The designated person must ensure that all pathologists and scientists involved in making morphological diagnoses fully participate in at least one EQA module relevant to their practice per year.

C5.3(i) Occasional or minimal involvement in EQA is not considered to represent full participation.

C5.3(ii) If a pathologist is a sub-specialist expert in a certain area of morphological pathology, it is expected that they participate in an EQA module relevant to that sub-discipline.

S5.4 Records relating to individual participation must be retained.

C5.4 Records **must** include documentation that the results have been reviewed, and where discordance is present, appropriate follow-up action has been taken.

S5.5 Where a laboratory submission to a morphological EQA program involves a collegiate response rather than the response of an individual, this must be noted on the submission.

C5.5 The benefits of individual enrolment in EQA activities should be considered in view of ease of record keeping and the continuity of a record for an individual.

Selection of EQA programs

S5.6 In assessing which EQA program is appropriate for a particular laboratory or test the laboratory must assess suitability against formal criteria and document this process.

C5.6 The relevant policies for selection of EQA programs by a laboratory should include:

(a) accreditation to ISO 17043[1]

(b) the aims of the programs, range of services and criteria for program selection

(c) documented procedures for participation in the selected program

(d) reporting procedures, suitability of data analysis and interpretation of results

(e) review mechanisms.

S5.7 Procedures must be developed to monitor the on-going assessment of results where there is no available EQA.

6. Introduction of a new assay or procedure

(Refer to Standard 4 and Standard 8B in *Requirements for Medical Pathology Services*)

This section should be read in conjunction with the TGA IVD Regulatory Requirements[†2].

S6.1 The designated person must ensure the laboratory has a documented procedure for the introduction of a new assay or procedure.

S6.2 The procedure and results of the validation/ verification must be approved and authorised as fit for purpose by the designated person.

S6.3 Validation and verification of quantitative methods before the implementation of the assay or procedure must include statistical correlation against existing validated methods, where available.

S6.4 For qualitative and semi-qualitative methods, studies of concordance with an existing validated method must be performed, where possible.

S6.5 Any method evaluation must include identification of sources of uncertainty of measurement.

[†] Regulatory requirements for in-house IVDs[2]

Reference List

1. International Organization for Standardization, *ISO/ IEC 17043:2010 Conformity Assessment – General requirements for proficiency testing*, International Organization for Standardization, Geneva

2. Federal Register of Legislation 2018, *Therapeutic Goods (Medical Devices) Regulations 2002*, Therapeutic Goods Administration, Canberra, viewed 17 January 2018, <https://www.legislation.gov.au/Details/F2018C00049>

Bibliography

Clinical and Laboratory Standards Institute 2017, *Harmonized Terminology Database*, Clinical and Laboratory Sciences Institute, viewed 17 January 2018, <http://htd.clsi.org/>

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