REQUIREMENTS FOR QUALITY CONTROL, EXTERNAL QUALITY ASSURANCE AND METHOD EVALUATION
(Sixth Edition 20xx)

Draft for public consultation – Jun 2017
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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 20xx) 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:

- Internal 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 Internal Quality Control system and an External Quality Assurance program must have in order to provide an effective monitoring strategy for the various pathology disciplines. This document also provides guidance on method evaluation for laboratories.
## Abbreviations

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

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Accuracy (of measurement)</td>
<td>means closeness of the agreement between the result of a measurement and the true value of the measurand.</td>
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<tr>
<td>Bias</td>
<td>means the systematic error of the measuring instrument.</td>
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<tr>
<td>Control Material</td>
<td>means a device, solution, or lyophilized 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.</td>
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<tr>
<td>Designated Person</td>
<td>means the same as the definition in the <em>Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories</em>.</td>
</tr>
<tr>
<td>Error</td>
<td>means the result of a measurement minus the true value of the measurand.</td>
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<tr>
<td>External Quality Assurance</td>
<td>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.</td>
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<tr>
<td>Imprecision</td>
<td>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 in fact measures of imprecision.</td>
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*Harmonized Terminology Database of the Clinical and Laboratory Sciences Institute*
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Inaccuracy</td>
<td>means the numerical difference between a value and the true value.</td>
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<tr>
<td>In house IVD</td>
<td>means the same as the definition in the <em>Therapeutic Goods (Medical Devices) Regulations 2002</em>. This is an IVD medical device that is:</td>
</tr>
<tr>
<td></td>
<td>(a) within the confines or scope of an Australian laboratory or Australian laboratory network</td>
</tr>
<tr>
<td></td>
<td>(i) developed from first principles, or</td>
</tr>
<tr>
<td></td>
<td>(ii) developed or modified from a published source, or</td>
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<tr>
<td></td>
<td>(iii) developed or modified from any other source, or</td>
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<tr>
<td></td>
<td>(iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and</td>
</tr>
<tr>
<td></td>
<td>(b) not supplied for use outside that laboratory or laboratory network.</td>
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<tr>
<td>Internal Quality Control</td>
<td>means operational techniques and activities at the point of use that are used to fulfil requirements for the quality of Medical Pathology Services.</td>
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<tr>
<td>Internal Quality Assurance (IQA)</td>
<td>means activities that aim to help monitor performance, drive improvement and support collaborative on-going professional practice. For example, these are activities that:</td>
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<td></td>
<td>• improve the quality of patient management and/or outcomes</td>
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<td>• focus on peer-review and technical audit</td>
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<td></td>
<td>• require documented evidence of a pathologist’s involvement</td>
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<td></td>
<td>• are practice based and developed in consultation with discipline advisory committees.</td>
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<td>Interpretative Tests</td>
<td>means tests where the result is based on pattern recognition utilising 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).</td>
</tr>
<tr>
<td>Measurand</td>
<td>means the quantity intended to be measured.</td>
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<tr>
<td>Precision</td>
<td>means closeness of agreement between independent test results from the same specimen obtained under stipulated conditions.</td>
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<td>Term</td>
<td>Definition</td>
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<tr>
<td>Qualitative Tests</td>
<td>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 (for example, 1+, 2+, 3+ as for urine drugs of abuse screening, pregnancy tests).</td>
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<tr>
<td>Quality</td>
<td>means the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>means part of quality management focused on providing confidence that quality requirements will be fulfilled.</td>
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<tr>
<td>Quality Control</td>
<td>means operational techniques and activities that are used to fulfil requirements for quality.</td>
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<tr>
<td>Quantitative tests</td>
<td>means tests whose output can be measured on a metric scale (for example, most clinical biochemistry tests and many haematological measurements).</td>
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<tr>
<td>Requirements for Medical Pathology Services (RMPS)</td>
<td>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.</td>
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<tr>
<td>Uncertainty</td>
<td>means a parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Validation</td>
<td>means confirmation by examination and the possession of objective evidence that the particular requirements for a specific intended use are fulfilled.</td>
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| Verification | means confirmation through provision of objective evidence that specified requirements have been fulfilled.$^\dagger$

Verification can comprise activities such as:
- performing alternative calculations
- comparing a new design specification with a similar design specification
- undertaking tests and demonstrations, and
- reviewing documentation prior to issue.

$^\dagger$ ISO 15189 *Medical laboratories-Requirements for quality and competence*
Introduction

The Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 20xx) is a Tier 3 document. It is issued by the National Pathology Accreditation Advisory Council (NPAAC) for the guidance of laboratories in Australia to provide the minimum standards considered acceptable when assessing participation 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 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.

In order 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 QC procedures, misinterpretation of EQA results and inadequate method evaluation to be common and thus important areas of risk. Satisfactory participation in External Quality Assurance is a requirement for all pathology laboratories seeking accreditation. External Quality Assurance testing programs must be available in order to establish standards of acceptability. External Quality Assurance 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. External quality assessment schemes compare testing outcomes of different laboratories to 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
Requirements for QC, EQA & Method Evaluation

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 comments 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

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 6 and Standard 7 in Requirements for Medical Pathology Services)

Quantitative results are reported numerically and are compared against 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 through the use of an appropriate quality control system comprising 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) Performance goals should be set based on both the measurand or procedure and the clinical situation.

C1.1(ii) Documentation should include the:

(a) selection of assays and procedures that are fit for purpose
(b) selection of target and ranges for QC samples
(c) acceptance criteria for QC and EQA results
(d) satisfactory performance in relevant EQA and IQA for all pathologists and the laboratory staff.
2. Analytical Quality Control

(Refer to Standard 6B and Standard 7 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 true performance of the test.

Selection of Quality targets for Quality Control samples

S2.2 The designated person must ensure that QC materials have concentrations that are within the boundaries of their method's measuring range, without dilution.

Setting (and re-setting) of Quality Control targets and acceptable ranges

S2.3 The designated person must determine the target SD for QC material using the laboratory analytical SD.‡

C2.3 Review of the QC running mean value and SD compared to targets should occur regularly and these should be reviewed each month, at a minimum.

Selection of Quality Control rules

S2.4 The designated person must select an appropriate QC algorithm to ensure detection of critical shifts in performance.

C2.4 Where analytical imprecision is poor relative to performance goals, good error detection may be difficult to achieve regardless of the QC algorithm used.

Frequency of running Quality Control

S2.5 The designated person must have a documented procedure for the frequency of running QC samples.

C2.5 QC specimens should be run anytime when the integrity of the clinical diagnostic instrumentation may be compromised, including with:

(a) reagent lot changes
(b) routine instrument maintenance
(c) calibration

‡ Clinical and Laboratory Standards Institute (CLSI) EPI5-A3 guideline
(d) new reagent packs, and
(e) if trends in patient results have shifted.

S2.6 The designated person must be involved in the regular review of QC.

C2.6(i) This review should include target and range review and follow
up/investigation of any trends or failures.

C2.6(ii) The review should include all relevant staff.

S2.7 The designated person must document the escalation process for any QC
failures.

S2.8 The designated person must have a documented procedure for all staff to follow
if there has been a QC failure.

C2.8 The designated person must be involved in the resolution of any significant
failures that impact on patient safety.

S2.9 The designated person must have a documented procedure for re-running any
patient samples that were measured between the last successful QC sample and
the first failed QC sample.

C2.9 Part of this process may include the review and retraction of previous
pathology results and issuance of corrected patient test results.
3. Internal Quality Assurance

(Refer to Standard 3, Standard 6A and Standard 7 in Requirements for Medical Pathology Services)

In areas of pathology where morphological diagnosis is made by individual pathologists or scientists, it is expected that all pathologists or scientists involved in making morphological diagnoses are involved in both IQA and EQA activities pertinent to their diagnostic activities. These areas of pathology include Anatomical Pathology, Cytology, Morphological Haematology and Cytogenetics and, in 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 IQA activities are distinct from quality control of reagents and laboratory staining processes.

S3.2 Activities relating to the pre-analytic (laboratory sample preparation), analytic (diagnostic) and post-analytic (report integrity and delivery) steps must be undertaken in all laboratories involved in morphological diagnosis.

C3.2 Examples of appropriate IQA activities are provided in the RCPA IQA Framework\(^\text{§}\), along with suggestions for recording such activities.

S3.3 All pathologists must participate in peer review activities as a component of diagnostic IQA.

C3.3(i) Records of peer-review diagnostic activities must be kept.

C3.3(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.

C3.3(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.

\(^\text{§}\) https://www.rcpa.edu.au
4. Pre and Post-Analytical Quality Assessment

(Refer to Standard 3, Standard 6A and Standard 7 in Requirements for Medical Pathology Services)

Although it is recognised that pre- and post-analytical factors are not always under the control of laboratories, these have a known impact on patient safety.

S4.1 Documented procedures must be in place for quality assessment of the pre- and post-analytical phases.

C4.1(i) Laboratories **must** measure and if necessary implement procedures to ameliorate any potential risks to patient safety.

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

C4.1(iii) Variables which can affect the pre-analytical phase of testing can include but are not limited to:

(a) patient identification
(b) patient preparation and availability of pre-test information
(c) clear procedures for correct specimen collection
(d) recording endogenous variables, e.g. current drugs, circulating antibodies
(e) specimen labelling
(f) recording of specimen integrity including correct tube fill, haemolysis, lipaemia, icterus
(g) incorrect specimen collection
(h) specimen transport
(i) turnaround time from collection to receipt and to validation.
(j) specimen ischaemic time prior to fixation (tissue specimens)
(k) duration and nature of tissue fixation.

C4.1(iv) Laboratories should be enrolled in an EQA program covering the pre-and post-analytical phases, where available. Laboratories not enrolled in such an EQA program should identify high risk areas and compare their data with other accredited laboratories to ensure they demonstrate acceptable performance. Variables which can lead to post-analytical error include:

(a) erroneous validation of analytical data
(b) failure in reporting/addressing the report
(c) excessive turn-around-time
(d) improper data entry and manual transcription error
(e) failure/ delay in reporting critical values.
5. **Enrolment and Participation in External Quality Assurance Programs**

(Refer to Standard 3 and Standard 7 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 is responsible for the enrolment, participation and evaluation 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.

**S5.2** Laboratory performance in an EQA program must be reviewed by the designated person.

**S5.3** 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.

- **C5.3(i)** The EQA must be reviewed and non-concordant results and failures must be investigated and documented in a timely manner with appropriate actions taken.
- **C5.3(ii)** There must be consideration of the potential risk posed to patients from the failure of the test procedure.
- **C5.3(iii)** The designated person must be informed of any significant failures at the earliest possible time.

**S5.4** 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.

- **C5.4(i)** Occasional or minimal involvement in EQA is not considered to represent full participation.
- **C5.4(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.

**S5.5** Processing and reporting of EQA materials must be performed in a similar manner to processing and reporting of routine samples received in the laboratory, wherever possible.
S5.6  Records relating to individual participation must be retained.

C5.6  Records **must** include documentation that the results have been reviewed, and where discordance is present, appropriate follow-up action has been taken.

S5.7  Where submission to an EQA program involves a collegiate response rather than the response of an individual, this must be noted on the submission.

C5.7  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.

S5.8  Submission of results from EQA programs must be within the programs’ deadlines.

Selection of EQA programs

S5.9  In assessing which EQA program is appropriate for a particular laboratory or test application, the laboratory must assess suitability against formal criteria and document this process.

C5.9  The relevant policies for participation in EQA programs by a laboratory should include:

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

(b)  documented procedures for participation in the selected program

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

(d)  review mechanisms.

S5.10  If an EQA program is supplied by an instrument provider, the results must be traceable to an internationally verified standard.

C5.10  This EQA program **must** also meet the requirements outlined in *Appendix A*.

S5.11  Procedures must be developed to monitor the on-going assessment of results where there is no available EQA.

C5.11  Procedures may include:

(a)  specimen exchange with other accredited medical pathology laboratories

(b)  comparisons using reference materials.
6. Method Evaluation

(Refer to Standard 6B in Requirements for Medical Pathology Services)

This section should be read in conjunction with the NATA Technical Note Guidelines for the validation and verification of quantitative and qualitative test methods.

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 prior to the implementation of the assay or procedure must include statistical correlation against existing validated methods.

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

S6.5 Any method evaluation must include identification of sources of uncertainty of measurement.
Appendix A  External Quality Assurance criteria  
(Normative)

The following criteria must be considered when assessing an EQA program:

(a) whether the program supplier is approved by a recognised accreditation body
(b) whether the programs address pre- and post-analytical components of testing
(c) the availability of direct assistance for resolution of technical problems
(d) whether the program supplier is supported by relevant pathology or other professional associations
(e) the selection of a program that has an appropriate peer group
(f) conformity with recognised safety standards for both the material and the method of distribution
(g) the suitability of associated instructions and documentation
(h) the range of constituents, tests or test procedures for the discipline in which the laboratory operates
(i) information on the suitability, stability and applicability of the material** for the testing under consideration
(j) the commutability of material to patient specimens, matrix compatibility and transit stability
(k) the frequency of material distribution to allow assessment of adequate performance.
(l) the frequency of analysis that is sufficient to provide statistically meaningful information
(m) the availability of reporting procedures which demonstrate current and long-term performance and provide a measure of acceptable performance and/or a ranking system
(n) the availability of submitted data and timeliness of report distribution to allow assessment of performance
(o) whether the program clearly distinguishes between educational and assessable material components
(p) whether the program provides regular communication to assist laboratories in improving their performances
(q) whether the program is designed to deter and detect falsification and collusion
(r) whether there is provision of documentary evidence of enrolment, participation and performance.

** Material includes programs such as Virtual Microscopy
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Bibliography


NATA Technical Note *Guidelines for the validation and verification of quantitative and qualitative test methods*, October 2013, NATA

Further information

Other NPAAC documents are available from:

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