

Internal Quality Assurance Framework

Haematology

The Royal College of Pathologists of Australasia received funding from the Department of Health, under the Quality Use of Pathology Program (QUPP) to develop a comprehensive framework for internal quality assurance, focused on the morphological disciplines of Histopathology, Cytopathology, Haematology and Forensic Pathology. The overall governance of this project was provided by the College, and was supported by a Steering Committee that included representatives of the morphological disciplines. The Board of Education and Assessment and the Board of Directors further decided to develop separate discipline specific Frameworks for the other disciplines of pathology.

The Haematology IQA Framework contains activities that will aim to help monitor performance, drive improvement and support collaborative on-going professional practice. The IQA Framework activities focus on peer-review and clinical audit and require documented evidence of a pathologist's involvement in these internal quality activities. The Framework is practice based and the Haematology Pathology Advisory Committee provided guidance with the development of the Haematology Pathology Framework activities.

Implementation of the Haematology IQA Framework will be undertaken in 2017 in consultation with the Fellowship.

For any queries about the Framework or the project, contact the DCEO, Dr Bronwen Ross at bronwen@rcpa.edu.au

Framework Features

The Internal Quality Assurance Framework divides activities into 3 specific cycles:

1. *Pre-analytic* phase of the test cycle is specimen delivery and accessioning, and laboratory technical processing.
2. *Analytic* phase of the test cycle in the current context relates to the pathologist diagnostic component.
3. *Post-analytic* phase of the test cycle begins with report authorisation through to report delivery, and may include adjunct activities such as billing.

The Framework records these activities under 2 sections:

Section 1: Diagnostic Measures (the analytic phase) relates to peer review activities, participation of 10 hours per annum required.

Section 2: Technical Laboratory Measures (pre-analytic) & Service Performance (post analytic/overview) relate to clinical audit activities, participation of 10 hours per annum recommended.

Please refer to the tables on the following pages for information on examples of suitable activities and document requirements.

FRAMEWORK
Internal Quality Assurance Activities
HAEMATOLOGY

Section 1: DIAGNOSTIC MEASURES - (engaging in peer review activities)

Requirement: Minimum 10 hours per annum Diagnostic Measures

Activity	Quality activity monitor related	Suggested document requirements	
Case Reviews Using clinical audit techniques	<ul style="list-style-type: none"> • Internal random case review <ul style="list-style-type: none"> - Defined % of cases 	Document the review type <ul style="list-style-type: none"> - Who performed the review - What was reviewed - What cases were reviewed - Time it took 	
	<ul style="list-style-type: none"> • Internal target case review <ul style="list-style-type: none"> - Specific case types 		
	<ul style="list-style-type: none"> • Internal correlations <ul style="list-style-type: none"> i) Bone Marrow Aspirate <ul style="list-style-type: none"> – Bone Marrow Aspirate deferral rate to paraffin section ii) Bone Marrow trephine, H & E +/- IHC iii) FBE films iv) Or other types of correlations performed 		Structure discordance as; <ul style="list-style-type: none"> - None (agreement) - Minor/ typo error - Minor discordance/ no effect on patient care - Major discordance /potential impact on patient care
	<ul style="list-style-type: none"> • Inter institutional correlations <ul style="list-style-type: none"> - 2nd opinions (incoming and outgoing) 		
	<ul style="list-style-type: none"> • Intradepartmental correlations <ul style="list-style-type: none"> - Formal 2nd opinions - Informal 2nd opinions 		
	<ul style="list-style-type: none"> • Multi Disciplinary Team (MDT) case presentations** <ul style="list-style-type: none"> - Any discordant opinions 	Document discordance <ul style="list-style-type: none"> - None (agreement) - Minor /non clinical - Minor / clinical - Major / clinical 	
	<ul style="list-style-type: none"> • Audit of corrected/ amended reports 		
	<ul style="list-style-type: none"> • Compliance with / utilization of structured report templates <ul style="list-style-type: none"> - Other (where available) 		
Formal Peer Review	<ul style="list-style-type: none"> • Validated 360 degree peer review completed 	Date, time and duration and brief description of activity.	

** The MDT meetings are the responsibility of the individual laboratory, and are expected to be documented and records maintained with the above criteria mentioned. Record any disagreement which may arise between the original diagnostic report and the MDT review. Issue an addendum post MDT if required and follow-up according to your individual laboratory policy for such incidents. Each laboratory must have documented processes for handling diagnostic discordances when detected.

For example: Correlation results:

Agreement – represents haematology / histopathology where all present and agree with the report.

Deferral rate - represents the cases where the bone marrow aspirate was deferred until final diagnosis was reached on paraffin sections. State reason for this in documentation; e.g. bone marrow aspirate slide difficult to report on due to, poor quality, not enough cells /inclusive or a difficult case and requires the paraffin section as well as bone marrow aspirate to make the final diagnosis.

Minor disagreement/discordance - represent where there is a small change in diagnosis but there is minimal or no clinical impact.

Major disagreement/ discordance - represent a significant difference between original diagnosis and the final diagnosis where potentially there is a significant impact on a patient's treatment or outcome.

FRAMEWORK Internal Quality Assurance Activities HAEMATOLOGY		
Section 2: TECHNICAL MEASURES - laboratory based non-conformances (audit activities)		
Requirement: Minimum 10 hours per annum combined Technical Measures/Service Performance		
Activity	Examples of quality monitors related to lab based non-conformances	Suggested document Requirements
<p>Non-conformance reporting</p> <p>A laboratory non-conformance is an incident that has the potential to cause an error or harm. Documentation of these is a requirement. Laboratories should have existing policies, procedures and processes in place if such an incident occurs. The examples stated in this table should be reported.</p>	<ul style="list-style-type: none"> • Specimen receipt issues* <ul style="list-style-type: none"> - Incorrect identifiers - Labelling errors - Lost specimens • Specimen handling issues • Laboratory technique issues <ul style="list-style-type: none"> - Staining - Special stains - Blood smears 	<p>- Incidence +/- % of non-conformances</p>
Section 2: SERVICE PERFORMANCE - suggested examples below of types of service activities that may Be monitored and specific data collected		
<p>Audit of Service Performance</p> <p>The goal is to monitor and improve internal laboratory performance using auditable measures and collecting acceptable data to develop benchmarks for the future.</p>	<ul style="list-style-type: none"> • Turn Around Times** <ul style="list-style-type: none"> - Whole workload or - Selected case type; E.g. blood films or bone marrow reports - Haemoglobinopathies - Flow Cytometry • Report format review <ul style="list-style-type: none"> - Typographical/ transcript errors - SNOMED – as per WHO ICD coding • Billing Errors 	<p>Documentation of TAT</p> <ul style="list-style-type: none"> - Overall - Different phases of reporting process - By different case types <p>% Errors concluding check</p>

* Laboratories must have policies for handling detected non-conformances

** For criteria from either current ACHS or RCPA recommendations

Establishing a Haematology IQA Framework that will be used to routinely review processes in the discipline should facilitate improved laboratory practices. It provides a mechanism for peer review, introduces a mechanism for laboratories to benchmark their processes to measure improvements, reduces the risk of aberrant/uninformative/false reports being issued in a clinical environment, thereby improving the quality of patient management and/or outcome.

Activities performed from the Haematology IQA Framework will be linked to the RCPA CPD Program and will likely be an important part of any Revalidation Framework the College may need to adopt in the future.

The completion of these activities could form part of the RCPA audit substantiation for the RCPA CPD Program in the future.