Internal Quality Assurance Framework

Immunopathology

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.

The Immunopathology IQA Framework contains activities that will aim to help monitor performance, drive improvement and provide a collaborative on-going professional practice process. 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 Immunopathology Advisory Committee provided guidance with the development of the Immunopathology Framework activities.

Implementation of the Immunopathology 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 bronwenr@rcpa.edu.au

Framework Features

The Internal Quality Assurance framework divides laboratory activities into 3 specific cycles:

1. *Pre-analytic* phase of the test cycle includes specimen delivery and accessioning, specimen handling 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 in 10 hours per annum required.

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

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

FRAMEWORK Internal Quality Assurance Activities IMMUNOPATHOLOGY		
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	• Internal targeted case review – *examples could include*: - Immunofluorescence microscopy – autoantibody patterns - Flowcytometry interpretation - Electrophoresis & Immunofixation interpretation - HIV interpretation	Document the review type - Who performed the review - What was reviewed - What cases were reviewed - Time taken
	• Internal correlations, or other types of correlations performed *examples could include*: - Internal flow cytology results/morphology/ cytology - Internal Quality Investigations (IQI)	Document discordance as - None (agreement) - Minor / non clinical - Minor clinical (no effect on patient care) - Major clinical (potential impact on patient care)
	• Inter institutional correlations – *examples could include:* - 2nd opinions (incoming and outgoing) - RCPAEQA case study series - Email case discussion group	
	• Intradepartmental correlations – *examples could include:* - Formal 2nd opinions - Informal 2nd opinions e.g. test results	
	• Multi Disciplinary Team (MDT) case presentations** *examples could include:* - Any discordant opinions	Document discordance - None (agreement) - Minor /non clinical - Minor / clinical - Major / clinical
Formal Peer Review	• 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 these are expected to be documented and records maintained, including 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 individual laboratory policy for such incidents. **Each laboratory must have documented processes for handling diagnostic discordances when detected.**

FRAMEWORK Internal Quality Assurance Activities IMMUNOPATHOLOGY		
Section 2: TECHNICAL MEASURES - laboratory based non-conformances (audit activities) **Recommended: Minimum 10 hours per annum combined Technical Measures/Service Performance**		
Activity	**Examples of quality monitors related to lab based non-conformances**	**Suggested document Requirements**
Non-conformance reporting 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.	• Specimen receipt issues* - Incorrect identifiers - Labelling errors - Lost specimens • Specimen handling issues • Laboratory technique issues • Root cause analysis & troubleshooting	Incidence +/- % of non-conformances
Section 2: SERVICE PERFORMANCE - suggested examples below of types of service activities that may be monitored and specific data collected		
Audit of Service Performance The goal is to monitor and improve internal laboratory performance using auditable measures and collect acceptable data to develop benchmarks for the future.	• Turn Around Times** - Whole workload; - Selected case type - Validation of reports at interface stage • Report format review - Typographical/ transcript errors - Inappropriate reporting e.g. Flow reporting • External complaints • Sub-audits - Clinical interpretations • Billing Errors • Audit of corrected/ amended reports	Documentation of TAT - Overall - Different phases of reporting process - By different case types % of Errors post audit Documentation of complaints - Type of complaint - Follow-up/outcome

Establishing an Immunopathology 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, reduce the risk of aberrant/uninformative/false reports being issued in a clinical environment, thereby improving the quality of patient management and/or outcomes.

Activities performed from the Framework may be linked to the RCPA CPDP 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.