Final Report

Genetic and genomic certification for non-genetic pathologists and trainees within individual scope of practice

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20 December 2019 [revised 16 January 2020]

RCPA
The Royal College of Pathologists of Australasia

Contents

1. Glossary of terms & acronyms

Acronym	Detail
AP	Australian Pathology
FELLOW	Member of the RCPA who has obtained Fellowship
Modules	RCPA Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)
NATA	National Association of Testing Authorities, Australia
NPAAC	National Pathology Accreditation Advisory Council, Australia
PPA	Public Pathology Australia
RCPA	Royal College of Pathologists of Australasia
RCPAQAP	RCPA Quality Assurance Programs
RPL	Recognition of Prior Learning
TECHNICAL ASSESSOR	Expert Pathologist qualified to assess applications

2. Executive summary

This is the Final Report for the Genetic and genomic certification for non-genetic pathologists and trainees within individual scope of practice Project.

The RCPA identified the need for non-genetic pathologists who supervise laboratories to be assessed against the competency requirements developed by the RCPA to satisfy individual genetic and genomic competencies and qualifications to meet the new NPAAC Requirements for Supervision in the clinical Governance of Medical Laboratories (NPAAC *Requirements*) due to take effect in 01 August 2019. The RCPA identified the need to implement a process and program to assess non-genetic pathologists who currently supervise laboratories where genetic and genomic testing is performed, and where required, to upskill individual supervising pathologists within their scope of practice to comply with the new NPAAC laboratory supervisory requirements.

The objective was to undertake a Recognition of Prior Learning credentialing process for non-genetic pathologists expressing interest in supervising laboratories performing genetic and genomic testing within their scope of practice. Suitably qualified panels of expert pathologists were formed to assess individual applicants based upon recognition of prior learning / experience who determined if certification was granted in discipline specific modules relevant to each Fellow's scope of practice. The Project activities targeted the existing supervision workforce to assess individual competency, and as a result the Project increased the pathologist workforce by an additional 86 pathologists who were deemed competent to supervise genetic testing in their disciplines.

The Project completed the following activities:

- Formed Steering Committee to oversee the Project and Pathology Expert Groups to assess applicants

- Established Assessor Panels for the five pathology disciplines under assessment – Anatomical Pathology, Chemical Pathology, Haematology, Immunopathology and Microbiology. The Project had a total of 40 Technical Assessors, 12 of which are genetic pathologists. [A genetic pathologist is required on each Assessment Panel].

- Promoted the RPL credentialing process amongst the RCPA Fellowship via RCPA fortnightly newsletter *Pathology Today*, RCPA website, RCPA annual conference – Pathology Update, Supervisor workshops and RCPA short courses, and through stakeholders such as NATA, Australian Pathology and Public Pathology Australia.

- Received and recorded applications from 125 individuals (269 Module applications) and 19 Category S Laboratory applications for assessment, of which over 95% applied for assessment against multiple modules within their relevant discipline.

- Of the Module applications assessed by the Technical Assessors, approximately 50% of these were classified as "simple" assessments (i.e. assessment time up to one hour); and the remaining 50% were classified as "complex" (i.e. assessment time up to 5 hours).

- The Project increased the pathologist workforce by an additional 86 pathologists who are competent to supervise genetic testing in their disciplines.

- The Project also identified that not all applicants were suitable to supervise genetic testing and further to this Project, the RCPA has developed a Module-based training and assessment pathway for pathologists to obtain competencies.

A number of challenges were encountered by the Project which included:

- Slow receipt of applications from prospective applicants. Approximately 50 per cent of all applications were received in the week ending 31 May 2019 (applications close date).

- Incomplete submissions where follow up caused delays in the assessment process.

- The number of Technical Assessors to efficiently undertake assessments was limited. The Project continued to actively identify and recruit new Technical Assessors to assist with ongoing management of this issue.

- Delayed turnaround times for assessment of Module applications. This was primarily due to the limited availability of the Technical Assessors and their conflicting work and other professional commitments.

- Assessors requesting additional information added to delays – which resulted in a “second round of waiting”.

- Appeals and reassessments resulted in additional workloads for assessors as recruitment of new assessors was required to undertake reassessments.

The assessment process highlighted the need for some applicants to undergo further training before proficiency could be granted and as at 20 December 2019, approximately 45 per cent of individual applicants were certified as unsatisfactory by Technical Assessors, and where appropriate pathologists can undertake the Module training and assessment pathway to obtain competencies in the future.

This Final Report outlines the Project outcomes.

3. Project statement

3.1 Background

The new NPAAC Requirements for Supervision in the clinical Governance of Medical Laboratories (NPAAC *Requirements*) due to take effect in 01 December 2019 highlighted the need for the RCPA to identify pathways for non-genetic pathologists who supervise laboratories to obtain competencies and qualifications to meet these genetic and genomic requirements. These new requirements require laboratories to upskill the existing non-genetic pathologists to be certified and competent to perform limited genetic and genomic pathology testing within their current scope of practice within a satisfactory timeframe. In Australia there were 22 qualified genetic pathologists and 8 registrars in training who are deemed competent to supervise laboratories performing genetic and genomic testing, and a likely shortfall in the number of suitably qualified laboratory supervisors to meet quality and demand once the NPAAC *Requirements* become effective. The RCPA identified the need to implement a process and program to assess non-genetic pathologists who currently supervise laboratories where genetic and genomic testing is performed, and where required, to upskill individual supervising pathologists within their scope of practice to comply with the new NPAAC laboratory supervisory requirements.

The RCPA developed certification criteria to ensure appropriately trained and qualified pathologists are in place who can advise the requesting pathologist, other specialist or general practitioner about the correct test. This structure will provide the most current scientific foundation for treatment decisions by certified and competent laboratory supervisors using genetic and genomic information as the basis for this decision making with the introduction of the new NPAAC *Requirements.*

4. Scope

4.1 Purpose

To implement a program and a process to identify and certify suitably qualified non-genetic pathologists who can supervise laboratories performing genetic and genomic testing services within their scope of practice in accordance with the new NPAAC *Requirements*, without compromising quality and / or service delivery.

4.2 Project objectives

To increase the number of suitably trained and qualified pathologists who can supervise laboratories performing genetic and genomic testing within their disciplines in accordance with the new NPAAC *Requirements* through RPL. The credentialing process, undertaken by a panel of suitably qualified expert pathologists, was based upon recognition of prior learning / experience to determine\ certification in discipline specific modules relevant to each Fellow's scope of practice.

Successful certification under this recognition of prior learning / experience enables non-genetic pathologists supervising laboratories to fulfil NPAAC *Requirements* in relation to genetic and genomic pathology testing.

Moving forward, the assessment process and program will provide a suitable pathway to determine individual upskilling requirements to ensure each laboratory supervisor is deemed to have the necessary scope of practice to meet the revised NPAAC *Requirements.*

4.3 Exclusions

The following are considered exclusions in delivering this Project:

- The development of any further certification modules associated with genetic/ genomic/ molecular testing and microbial genomics.
- The review of any of the medical pathology trainee and post fellowship curricula
- The engagement of the disciplines of Forensic Pathology or the standard genetic pathology Fellowship to review trainee curriculums or develop certification modules associated with genetic/ genomic/ molecular testing and microbial genomics.

5. Governance

The governance model identified by the Project provides the decision-making framework for all levels of the Project allowed interconnectivity between the Project Steering Committee, Pathology Expert Group, Technical Assessors, the RCPA Board of Directors, RCPA Board of Education and Assessment, and the Project Team. The RCPA Board of Directors approved the strategic intent of this Project and the Project Steering Committee developed a Project Plan to manage the deliverables.

5.1 Steering Committee

The Project Steering Committee reported to the RCPA Board of Directors and included RCPA Genetic Pathology Chief Examiner, and representatives from the RCPA Management Team. The Steering Committee comprised: -

- RCPA Chief Executive Officer
- RCPA Chief Examiner – Genetic Pathology
- RCPA General Manager – Operations
- RCPA Manager, Project Management Office
- RCPA Project Officer

The Steering Committee is responsible for the coordination and oversight of the Project, including the assessment process for individual applicants under the RPL. This included project deliverables, meeting the key performance indicators and management of the financial budget. The Steering Committee were also responsible for promoting all Project activities regarding the application and credentialing process, assessment panel composition, timeframe for assessment, outcomes of assessment and other relevant material or timeframes regarding the *NPAAC Requirements*. The Steering Committee met regularly and received formal recommendations from the Technical Assessors when assessments were finalised. The Technical Assessors provided the Steering Committee with the recommendations from the formal assessments. The Steering Committee submitted recommendations to the RCPA Board of Education and Assessment for endorsement, and finally to the RCPA Board of Directors for final approval. If the assessment outcome was unfavourable, the Steering Committee worked with the Pathology Expert Group to provide adequate feedback to the applicants.

5.2 Pathology Expert Group

The Pathology Expert Group reported to the Steering Committee and provided expert technical and professional advice regarding genetic and genomic pathology knowledge and understanding associated with certification assessment process undertaken by this Project. The Pathology Expert Group worked with the Steering Committee to ensure the principles of the RPL were upheld and the assessment of each application was conducted with the highest level of integrity. The Pathology Expert Group comprised: -

- RCPA Chief Examiner – Genetic Pathology
- Former RCPA Chief Examiner – Genetic Pathology

The Pathology Expert Group provided valuable support and advice to the Technical Assessors / Assessment Panels where complex determinations were required. In the event of appeals, the Pathology Expert Group determined final outcomes.

5.3 Assessment Panel

The Project determined there were five pathology disciplines which required individual non-genetic pathologists to participate in the RPL to supervise laboratories performing genetic and genomic testing within their scope of practice.

- Anatomical Pathology
- Haematology
- Chemical Pathology
- Immunopathology
- Microbiology

The Project identified the assessment of each module required a minimum of two Technical Assessors, “the Panel” (Chief Examiner – Genetic Pathology or delegate; Chief Examiner – relevant discipline or delegate). The Assessment Panel for each discipline comprised of Technical Assessors as above who were responsible for assessing each Module relevant to the applicants’ discipline for all non-genetic pathologists who sought certification through the RPL.

5.4 Governance Structure

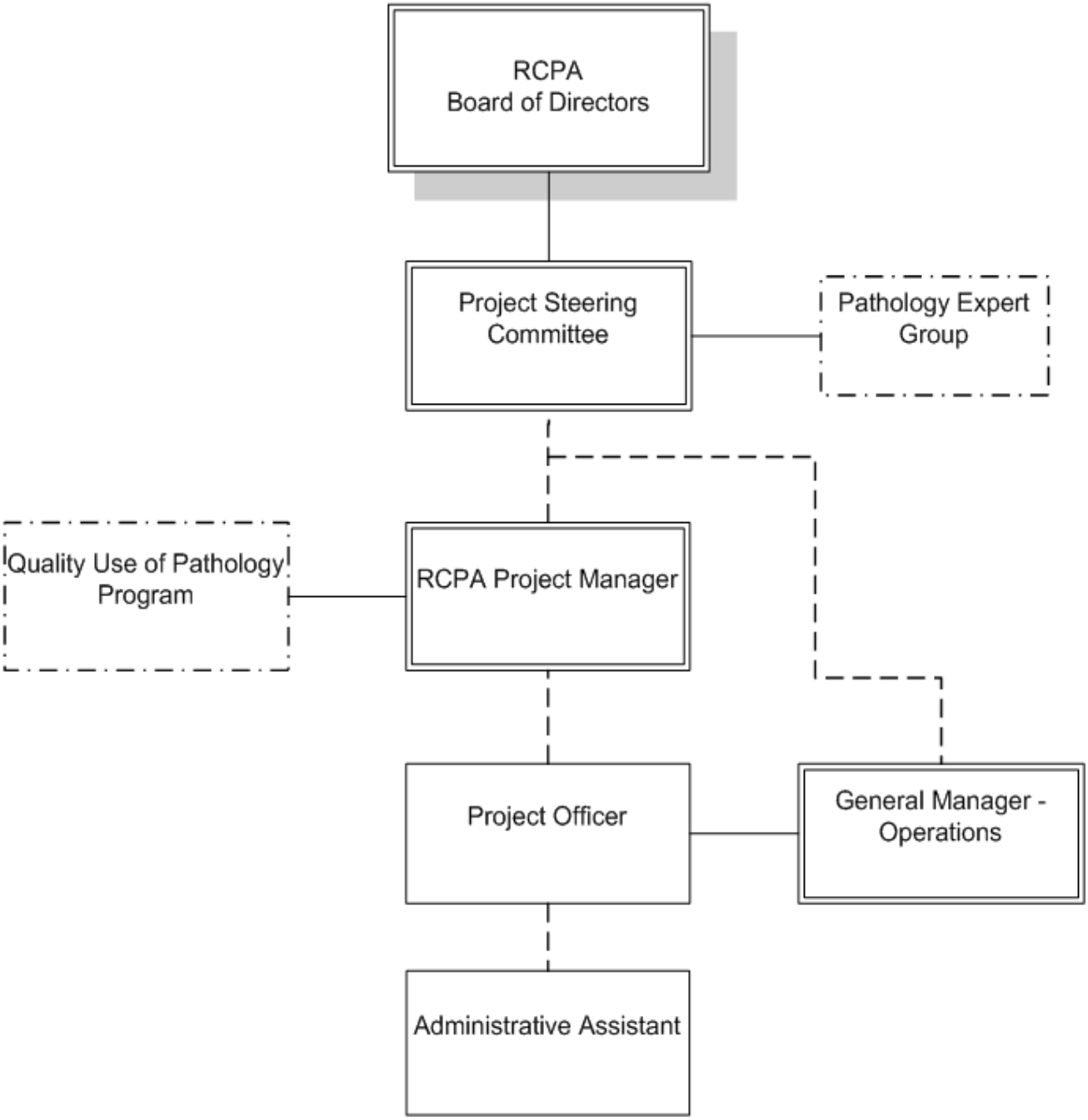

Figure 1: ***Project Governance Structure***

6. Project Activities

There were two key parts to the Project approach – call for expressions of interest, and the assessment and certification of applicants.

6.1 Work Activity (Phase 1 – Expressions of Interest)

- The Project called for Expressions of interest for RPL from the RCPA membership for individuals who already had the expertise required to supervise a restricted range of testing, who are doing so in a NATA/RCPA-accredited environment, and who have a sound performance record in relevant external quality assurance programs.

- Applicants were required to complete the application form together with the template addressing the assessment criteria (relevant to the applicant's discipline). The completed template required endorsement by the head of department/service/medical director. Applicants were required to submit evidence of the following:

    - Covering Letter addressing the recognition of prior learning criteria
    - CV (including a list of your previous employment & relevant publications)
    - Certified copies of Qualification (primary, additional and specialist)
    - Certified copies of Medical and Specialist Registration
    - List of tests (applied to enable supervision)
    - Quality assurance program reports
    - Continuing professional development requirements met

- The EOI process sought to prioritise those applicants who required immediate assessment to allow the medical practitioners to comply with NPAAC's supervision requirements. This was to address short term supervision requirements,however this pathway will remain open for future applicants. Assessment priority was as follows:

    - Must be currently supervising molecular testing with a clinical governance role within a pathology service in any Australian State or Territory;
    - Will be deemed to become the 'Primary' Designated Person as of 01 December 2018.
    - Be considered a 'Secondary' Designated Person in an institution that will/may require coverage of a 'Primary' Designated Person due to leave requirements
    - All other applicants

- The formal closing date for applications was 31 May 2019, however as at 20 December 2019, the Project received and recorded submissions from 125 individual applicants (269 Module applications) for assessment, and 19 Category S Laboratory applications.

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6.2 Work Activity (Phase 2 – Review and Assessment)

- Of the 125 individual applicants (269 Module applications) received for assessment, over thirty percent of these required requests for further information during the initial desk audit phase. Requests included: missing RCPAQAP reports, noncompletion of the application form, no authorised sign off from Department Head/Directors on application form, applicant not a financially compliant Fellow of the College and noncompliance with current RCPA Continuous Professional Development Program (CPDP).

- Of the 125 individual applicants (269 Module applications), the Project assigned these to Technical Assessors in order of priority. Primary designated persons were allocated the highest priority for assessment which was approximately 48 per cent of individual applications received.

- Assessment Panels (comprising two Technical Assessors as outlined in Section 5.3) established for all five disciplines to undertake RPL against RCPA Modules. There were 40 Technical Assessors confirmed throughout the Project, 12 of which were genetic pathologists. [A genetic pathologist was required on each Assessment Panel].

- A quality benchmarking teleconference with the Pathology Expert Group was held on 30 April 2019. The Group agreed on the requirement to undertake spot check audits to ensure a level of consistency in the quality and rigour of the RPL being undertaken across all assessors

- Technical Assessors requested additional information from over sixty five percent of individual applicants, primarily for missing information or forinadequate examples and evidence provided.

- 144 applications completed in total, of which 125 were individuals (269 Module applications), and 19 were individuals from Category S Laboratories. Of these, over 95% applied for multiple assessments against different modules within the disciplines, 86 individual applicants (133 Module applications) and six Category S laboratory applicants were successful and formally ratified by the RCPA Board of Directors.

- Limited scope of practice credentialing was discussed and supported by NPAAC and NATA at the stakeholder meeting held on 12 June 2019. This approach enabled pathologists who did not meet the full competency standard of an entire Module to obtain limited scope certification. The pathologists falling into this category were certified to practice with a limited additional scope to support the current service delivery of their laboratory, and as at 20 December 2019, 13 pathologists were granted limited scope of practice.

- As already evidenced, there were applicants who did not meet the competency standard to obtain certification of one or more Modules. Unsatisfactory applicants have received formal notification detailing the Module criteria which was not met and where applicable how these can be satisfied through the training and assessment pathway. Of the unsatisfactory applicants who appealed to the Technical Assessors' ruling through the established RCPA appeal processes, 29 Module application appeal outcomes are yet to be finalised. These will form part of RCPA ongoing assessment activities.

- Table 1 below shows the number of individual applicants to the number of Module applications received for each discipline, and from Category s Laboratories

Table 1:

Discipline (Individual Applicants)	**Submitted Individual Applicants**	**Submitted Module Applications**	**Withdrawn Modules**	**Appeal** (Re-assigned to Technical Assessor)	**Certified - Satisfactory** (Endorsed by the BOD)	**Certified Unsatisfactory**
	Individual	*Modules*	*Modules*	*Individual (Modules)*	*Individual (Modules)*	*Individual (Modules)*
Anatomical Pathology	27	44	0 (0)	4 (8)	19 (24)	10 (12)
Chemical Pathology	8	16	1 (1)	1 (3)	4 (5)	4 (7)
Haematology	35	88	18 (19)	2 (7)	25 (38)	16 (24)
Immunopathology	22	35	0 (0)	3 (4)	19 (22)	6 (9)
Microbiology	26	47	3 (3)	5 (7)	18 (28)	7 (9)
General Pathology	7	39	1 (2)	0 (0)	1 (16)	6 (21)
TOTAL	**125**	**269**	**23 (25)**	**15 (29)**	**86 (133)**	**49 (82)**
Discipline (Category S Laboratory**)**	**Category S Applicants**		**Withdrawn**	**Delayed Assessment / Under Review**	**Certified - Satisfactory** (Endorsed by the BOD)	**Certified Unsatisfactory**
Chemical Pathology	3		0	1	3	0
Genetic Pathology	6		0	1	0	5
Microbiology	1		0	0	0	1
Other – genetic	4		0	3	1	0
IVF – Andrology	2		0	0	2	0
IVF – Genetics	3		1	0	0	1
TOTAL	**19**		**1**	**5**	**6**	**7**

NB: An Individual can be included in any of the 4 columns – Withdrawn; Under Review; Certified Satisfactory; Certified Unsatisfactory – therefore the total number of Modules assessed is most relevant and tallies to the total in column "Submitted Module Applications".

7. Project Challenges

The short time frame in which to undertake and deliver this Project predictably created some challenges. The new NPAAC Requirements which took effect on 01 August 2019 placed additional workload pressure on the small number of pathologists who were technically qualified to undertake the development of the Modules in five disciplines. In addition, there was a small number of technically qualified assessors with competing work priorities and other professional commitments who were required to assess individual applicants within the short timeframe.

Notably the challenges experienced included:

- Managing the availability of the Pathology Expert Panel from within the small pool of 22 qualified Australian genetic pathologists. There continues to be a high demand for the services provided by genetic pathologists, and work and other professional commitments unfortunately often took priority over the activities of this Project. The Project navigated these conflicts and provided work arounds where possible to meet Project timelines

- Applicants were slow in submitting applications to be assessed through the RPL. A cumulative total of applications received by month below:

    - As at 15 April 2019 — 38 applications received
    - As at 17 May 2019 — 48 applications received
    - As at 24 May 2019 — 58 applications received
    - As at 31 May 2019 — 118 applications received
    - As at 20 December 2019 — 125 applications received

- The application process prioritised primary designated persons over secondary and/or aspirational applicants. For this reason, the Project established that many secondary applicants delayed submitting their applications until there was an outcome determined for their laboratory primary designated person.

- Technical Assessors assessed each applicant independently and the return rate of assessment showed approximately 50 per cent of Technical Assessors agree with their co-assessor in deeming an applicant satisfactory for certification. The remaining fifty per cent, required harmonisation and consensus assessment teleconferences with Assessment Panels which impacted the time taken to complete assessments. However, this was the agreed assessment harmonisation and consensus process to ensure a high quality standard of assessment was consistent amongst assessors.

- The Project continually reviewed strategies to overcome scheduling delays and to better manage turn-around times of individual assessments. Some of these included:
    - Expanding the number of Assessment Panels by recruiting additional qualified Technical Assessors;

    - Inviting Assessment Panels to the RCPA (i.e. offsite of their current employment) to undertake 1 - 2 day group assessments with the aim of reducing distractions from the workplace and/or other professional commitments which have largely slowed the assessment process. The Project realised focussed offsite group assessments lead

to more efficient assessment turnaround times as well as provided a professional forum for discussing and resolving issues related to more complex applications.

- Off-site focussed assessments enabled review of applications in a timelier manner and provided a more cost-effective way to review and certify the applications.

8. Project Outcomes and Future Directions

The Project was able to successfully meet the aim of expanding the number of suitably qualified pathologists who can supervise genetic and genomic testing services in accordance with the new NPAAC Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (NPAAC *Requirements*). The Project successfully granted certification in discipline specific modules relevant to each Fellow's scope of practice to an additional 86 pathologists, and 6 Category S laboratories. This increase in qualified pathologists from within the existing workforce will greatly assist with meeting the future service provision needs without compromising quality and/or service delivery in a timely manner.

Laboratories without appropriate supervision in place by 01 August 2019 were advised by the RCPA to have a risk management plan and clinical governance processes in place including how they plan to remedy the lack of appropriate supervision including time frame.

RCPA will continue to progress the 15 Individual applications (29 Module applications) that are ongoing. The process of assessing applicants against the RCPA Module criteria will continue to be used as the basis of assessment for any future applicants wishing to seek RPL. Successful applicants will be eligible to fulfil NPAAC requirements to supervise the defined range of tests in the Category of Laboratory in which they have been assessed against. This will also include the additional expectation to maintain continuing professional development specific to scope of practice, and the RCPA may request and audit individual professional development records to confirm this.

The RPL assessment outcome will be restricted to the field of testing directly related to those qualifications and competencies and current Scope of Practice. The RCPA expects it will continue to receive applications under the RPL pathway into the future and will implement a cost recovery process to administer assessment of new applications and ART laboratories as these applications will fall outside this Project.

However, for those unsuccessful applicants, including unsuccessful appeal applicants, who received a formal unsatisfactory notification which detailed the Module criteria which had not been met under the RPL process, will be provided with further advice regarding the RCPA training and assessment pathway and encouraged to progress this pathway where relevant. This will require applicants to complete a series of Modules developed by the RCPA which will require formal examination and assessment. This training and assessment pathway will be available going forward.

The RCPA is aware that pathology service delivery post 01 August 2019 will require ongoing monitoring and management, will continue to remain vigilant and responsive and will continue to assess new applicants under the training and assessment pathway into the future.

In addition, approval for the development of Biochemical Genetics 12-month Diploma has been received from the RCPA Board of Directors and RCPA Board of Education and Assessment which will assist with providing a solution to the shortage of pathologists able to supervise biochemical genetics testing. Development of the associated curriculum will commence in the new year and the RCPA will promote this opportunity amongst the Fellowship. This will allow Chemical Pathologists or Molecular Genetics Pathologists who successfully complete this Diploma to supervise biochemical genetics testing.