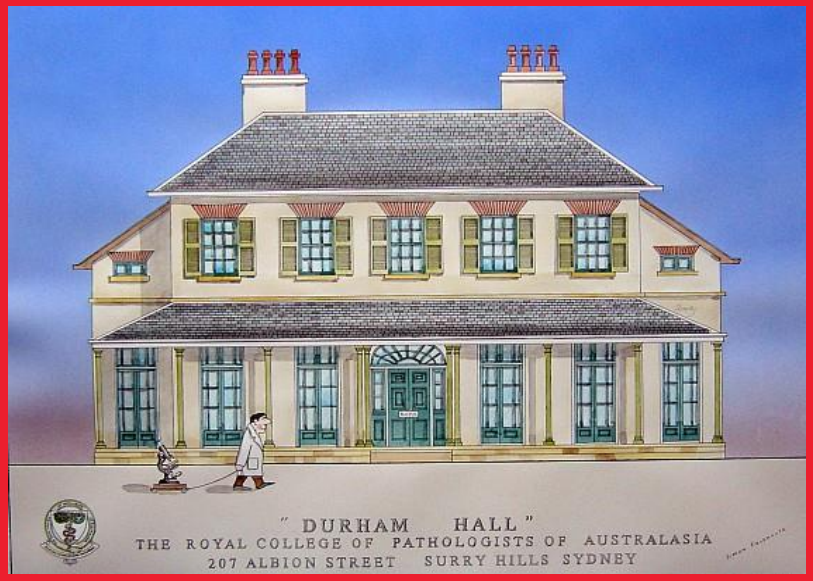
Management & Clinical Governance of Medical Laboratories



Clinical Privileges and Scope of Practice

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RCPA
The Royal College of Pathologists of Australasia

Definitions and purpose

Clinical Privileges and Scope of Practice

- Australian Commission on Safety and Quality in Healthcare Standards
  - This process is well established in all areas of medicine
- National Pathology Accreditation Advisory Council Requirements
- RCPA Policies and Procedures

Australian Commission on Safety and Quality in Healthcare (ACSQH)

The ACSQH wrote the 8

'National Safety and Quality Health Service Standards (2nd edition)'

Standard 1: Clinical Governance

Leaders of a health service organisation have a responsibility to the community for ***continuous improvement of the safety and quality of their services****, and ensuring that they are person centred, safe and effective.*

Intention of the standard

"To implement a clinical governance framework that ensures that patients and consumers receive safe and high-quality health care."

https://www.safetyandquality.gov.au/our-work/assessment-to-the-nsqhs-standards/nsqhs-standards-second-edition/

NSQHS Standard 1

Action 1.23: Credentialing and Scope of Clinical Practice

'The health service organisation has processes to:

a. Define the scope of clinical practice for clinicians, considering the clinical service capacity of the organisation and clinical services plan.
b. Monitor clinicians' practices to ensure that they are operating within their designated scope of clinical practice.
c. Review the scope of clinical practice of clinicians periodically and whenever a new clinical service, procedure or technology is introduced or substantially altered.

NSQHS Standard 1

- Action 1.24 The health service organisation:
  a. Conducts processes to ensure that clinicians are credentialed, where relevant
  b. Monitors and improves the effectiveness of the credentialing process

- Please note most State and Territory Governments have their own requirements for credentialing and scope of practice for the public sector

ACSQHC Definition of Credentialing

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

A formal process used to verify the

- experience
- professional standing and
- other relevant professional attributes

of health practitioners for the purpose of forming a view about their

- competence
- performance and
- professional suitability

to provide

- safe
- high quality health services

within specific organisational environments.

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ACSQHC Guide

- ACSQHC has a Guide: ‘Credentialing health practitioners and defining their scope of practice 2015’
- https://www.safetyandquality.gov.au/our-work/credentialing

- Defines best practice approach

ACSQHC Evidence of Minimum Credentials

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

1. Education, qualifications and formal training
2. Evidence of previous experience
3. Practitioner reference checks
4. Continuing education/peer review
5. Registration/recency of practice
6. Professional indemnity insurance
7. Other issues eg criminal checks etc

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ACSQHC Credentialing

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

- To define what the practitioner can do in their normal practice given where they are practicing.
- Sometimes there will be limitations of scope of practice due to issue affecting the individual or where the individual is practicing.
- Sometimes there may be an extension of the normal scope of practice granted to a particular specialist e.g. new technology when they are able to demonstrate appropriate training and experience.

ACSQHC Credentialing

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

- Important to have mechanism for regular review of scope of practice.
- Also mechanism for change in scope of practice.

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ACSQHC Credentialing Committee

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

The **formally constituted committee** of **practitioners** and **managers** who collectively analyse and verify the information submitted by the applicant, consider credentials and make a determination on the scope of clinical practice for a health practitioner. The membership of the credentialing committee should **include and preferably be led by**, representatives from the **professional group whose scope of practice is being determined**.

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NPAAC and Clinical Privileges and Scope of Practice

- The revised *'Requirements for the Clinical Governance and Supervision of Medical Pathology Laboratories'* was released by the Australian Government Department of Health in late June 2018.
- The *Requirements* will come into effect on Thursday 1 August 2019.

NPAAC Clinical Governance

"Means a systematic and integrated approach to assurance and review of clinical responsibility and accountability that **continually improves quality and safety of services** provided to patients resulting in optimal patient outcomes. Clinical governance extends across the boundaries of functions and organisation delivering services along the whole patient care path. **Interfaces in, or split responsibility for, delivering patient care are considered points of increased risk**."

https://www.health.gov.au/internet/main/Publishing.nsf/Content/health-npaac-docs-supervision.htm

NPAAC Scope of Practice

Means the discipline and/or areas of testing in which a person

1. has been trained and successfully **examined or assessed as competent** by the relevant College, professional society, or credentialing body and
2. in which they have met **current Continuing Professional Development** and
3. **recency of practice** requirements
   https://www.medicalboard.gov.au/News/2016-09-29-revised-registration-standards.aspx

NPAAC Credentialing Body

"Means the **formally constituted committee** of **practitioners** and **managers** who collectively analyse and verify the information submitted by an applicant, consider credentials and make a determination on the scope of clinical practice for a health practitioner.

The membership of the credentialing committee should **include**, and **preferably be led by, representatives** from the professional group **whose scope of clinical practice is being determined**."

NB: Same definition as ACSQHC

Supervision Requirement S1.1 and C1.1

S 1.1 Every laboratory must be under the direction and control of a Designated Person who is a medical practitioner and who is responsible for and accountable for the clinical governance of the Medical Pathology Service

C 1.1 The Designated Person may delegate to another medical practitioner with the relevant Scope of Practice to personally supervise the rendering of pathology services in a Category GX, GY or Category B laboratory

Designated Person

'The Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)'

"Means a registered medical practitioner with appropriate qualifications, competence and relevant Scope of Practice who has responsibility for the clinical governance of the laboratory and provides oversight and management of staff and processes to ensure ethical patient care and the provision of accurate and timely test results."

(In a GX lab, must be a full time pathologist)

Category GX Labs and Delegation

A Medical Pathology Service comprising a laboratory, or a number of co-located laboratories, performing services in one or more Groups of Pathology Testing:

- under the full time supervision and clinical governance of a Designated Person who must be a Pathologist, and
- where responsibility for full time onsite supervision of pathology testing may be delegated to other Pathologists with relevant Scope of Practice. These Pathologists may further delegate supervision of specific testing to Clinical Scientists with the relevant Scope of Practice.

Other laboratory categories

- GY:
  - Related to GX laboratory
  - Pathologist supervision onsite full time in aggregate for one or more disciplines
- B (Branch):
  - Related to GX or GY laboratory
  - Pathologist supervision can be remote with regular visits
- S (Specialised):
  - performing a limited range of pathology tests, for a target patient population, under the supervision of a Medical Practitioner with specialist qualifications and competency in the field of those tests and who is not a Pathologist.
- M (Medical)
  - Limited range, non-Pathologist, only for patients of the practice, co-located with the practice (eg blood gases in an ICU)

https://www.health.gov.au/internet/main/Publishing.nsf/Content/health-npaac-docs-supervision.htm

RCPA Scope of Practice

- The RCPA defines the scope of practice for pathologists on what is contained in the **current** curriculum for Trainees of the College
- It is an expectation that Fellows will maintain their competency against the curriculum via **continuing professional development** in their area of practice
- If they do not have **recency of practice** in an area then some form of supervised retraining may be required (apply to RCPA BEA).

https://www.ahpra.gov.au/Registration/Registration-Standards/Recency-of-practice.aspx

https://www.rcpa.edu.au/Library/College-Policies/Position-Statements/Pathologist-Recency-of-Practice

New NPAAC Supervision Requirements

- During 2017 a draft of NPAAC's New Supervision Requirements raised some questions for the College.
- The draft proposed strengthening Clinical Governance arrangement for laboratories and a change as to who would be acceptable to supervise.
- The College identified the need to develop a suite of educational training packages to upskill current Fellows of the College to ensure that they will be able to meet the proposed revised requirements.

New NPAAC Supervision Requirements

- During 2017, two consultative meetings were held with representatives of BEA, ACs and Fellows practicing Genomics.
- A recommendation was made that there needed to be a two (2) tier approach to these education and training issues.
- **Tier 1: All pathologists need to be literate in molecular pathology and this needs to be fully integrated into practice, and**
  Tier 2. Pathologists who wish to supervise genomic testing
- The above recommendation was submitted to both the RCPA Board of Education and Assessment and the RCPA Board of Directors and was agreed upon unanimously.

New NPAAC Supervision Requirements

- A Curriculum Development and Assessment Officer was appointed to assist the process.
- Discipline-specific Working Groups (WG) were established and workshops held.
- The Chief Examiner and Past Chief Examiner in Genetics were included in all WGs.
- Forensic Pathologists are currently not performing genomic testing so Working Group was not formed.

New NPAAC Supervision Requirements

Each Working Group looked at

- Tier 1 requirements, ie further strengthening of existing curriculum – ongoing.
- Development of a modular approach for Tier 2.
  1. Recognition of prior learning pathway or
  2. Training and assessment pathway

”It is acknowledged that this is a complex and constantly changing environment and the content of the modules and approach may be required to be amended in the future.”

https://www.rcpa.edu.au/Library/Practising-Pathology/NPAACSupCertMods

Recognition of Prior Learning

For Pathologists who

- already have the expertise required to supervise this testing,
- are doing so in a NATA/RCPA-accredited environment, and
- have a sound performance record in relevant external quality assurance programs.

Anatomical Pathology

"Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)"

- **Module 1** – Screening for known and unknown somatic genome variants in gene(s) associated with specified clinical phenotypes.

- **Module 2** – Screening of all chromosomes for known and unknown genomic variants (microscopy-based karyotyping and chromosomal microarray).

- **Module 3** – Sequence-based testing for known and unknown variants in multiple genes, including genes potentially linked to clinical phenotypes not previously diagnosed in the patient.

Chemical Pathology

"Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)"

- **Module 1** – Targeted testing for presence/ absence of predefined genomic variation by molecular methods.
- **Module 2** – Targeted screening for undefined variants in genes associated with specified clinical phenotypes.
- **Module 3** – Sequence-based screening for known and unknown variants in multiple genes, including genes potentially linked to clinical phenotypes that have not been previously diagnosed in the patient.
- **Module 4** – Cell Free DNA (cfDNA) and Single Nucleotide Polymorphisms (SNPs) for the purpose of Non-Invasive Prenatal Screening (NIPS).

Haematology

"Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)"

Module 1 – Targeted testing for presence/ absence of predefined genomic variation associated with malignancy, by molecular methods.

Module 2 – Targeted testing for presence/ absence of predefined genomic rearrangements associated with haematological/ solid tumours, by FISH microscopy.

Module 3 – Targeted screening for undefined variants in genes associated with specified clinical phenotypes.

Module 4 – Untargeted screening for known and unknown variants across the genome by microscopy/ karyotyping or DNA microarray analysis.

Module 5 – Sequence-based screening for known and unknown variants in multiple genes, including genes potentially linked to clinical phenotypes that have not been previously diagnosed in the patient

Immunopathology

"Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)."

Module 1 – Targeted testing for presence/ absence of predefined genomic variation associated with immunological disease, by relevant molecular methods.

Module 2 – Targeted screening for undefined variants in genes associated with specified clinical phenotypes associated with immunological disease.

Module 3 – Sequence-based screening for known and unknown variants in multiple genes, including genes potentially linked to clinical phenotypes that have not been previously diagnosed in the patient.

Microbiology

"Extension of Scope of Practice in Molecular Genetics (NPAAC Supervision Certification Modules)"

Module 1 – Pathogen identification and characterisation using genome data.

Module 2 – Pathogen genomics for the determination of relationships between isolates / generation of a phylogeny.

Module 3 – Microbiome. In development - will cover metagenomics and specimen-based sequencing.

Recognition of Prior Learning (RPL)

- Will need to have scope of practice approvals by 1 August 2019 to be compliant with Requirements.
- Applications in by 31 May to be processed by this time.
- Initial process only for those supervising (>100).
- RPL will be available on an ongoing basis.

Recognition of Prior Learning

- Knowledge Base
  - Relevant educational courses, seminars, workshops and personal or group study for continuing professional development.
- Clinical supervisory experience
  - Current and past relevant professional roles and service-related activities.
- Quality assurance and clinical governance
  - Quality improvement activities, internal or external quality assurance related activities.
- Research and development
  - List of relevant publications
- Continuity/ recency of practice
  - Documentary evidence briefly describing the overall duration and continuity of practice pertaining directly to the module, and the extent of involvement within the past three years.

Recognition of Prior Learning

- Self Assessment Process
- Assessors Process
  - Chief Examiner in Discipline and Chief Examiner of Genetics or Delegates
  - Complex applications may required interview, laboratory visit

Modules for Training and Assessment

- All modules are now available on the RCPA website for Trainees/Fellows wanting to extend scope of practice.
- Fellows who apply for but do not receive RPL may need to do further training and assessment.
- Trainees will be able to start documenting cases/techniques during training but will not be able to complete assessment until a Fellow.

https://www.rcpa.edu.au/Library/Practising-Pathology/NPAACSupCertMods