Scope of Practice of the Scientific Workforce of the Pathology Laboratory

Pathology testing is a key medical service carried out at the request of doctors. Pathology laboratories are staffed by pathologists, senior scientists, scientists, technicians, technical assistants and other support staff. The production of timely and accurate results for referred patients requires the collaborative efforts of all laboratory staff. This document describes the Scope of Practice of scientific and technical staff.

The role that medically qualified pathologists play in supervising the cycle of patient care from test selection to reporting and interpreting results lies outside of the scope of this document.

Competency Based Standards

Competency Based Standards for Scientific Workforce of the Pathology Laboratory reflect the work performed by staff of different levels of qualification, skill, experience, responsibility and accountability.

The first six units are, by definition, general competencies whereas the last four represent advanced competencies expected of staff performing supervisory or management roles. It is intended that these standards be suitable for assessment of competency in a specific discipline or across several disciplines.

The units and elements in the Competency Based Standards form the structure for the Scope of Practice document. Together these documents will provide the basis for future certification of Medical Scientists (Pathology).

Competency Based Scope of Practice

Although the competencies in the document are initially described for Medical Scientist (Pathology), they are not specific for this group. Some competencies, such as clerical or technical work or interpretation, may be common to several different groups of staff, but can be practised at different levels or in different contexts. As a result, these same competencies may be applicable to all groups of staff in the scientific workforce of the pathology laboratory, commensurate with their position or role.

The Scope of Practice document ***(Appendix 1)*** seeks to break down the various units and elements described in the Competency Based Standards into laboratory related tasks. These tasks or competencies are colour coded for the **minimum** level or qualification of staff involved in performing them. As such the competencies are cumulative i.e. a scientist should be able to undertake duties which are assigned as a minimum level to laboratory assistants, technicians and scientists, but the degree to which these tasks are undertaken will depend on their role.

Details are shown in the table below.

Colour	**Minimum level of staff required to perform task**
Yellow	Laboratory Assistant
Green	Medical Technician (Pathology)
Blue	Medical Scientist (Pathology)
Pink	Senior Scientist

Role Definition for Medical Scientists and Medical Technicians (Pathology)

It has become evident that role re-definition is required so scientific staff are removed from routine, and often more technical, testing. As such, their scientific skills could then be utilised in more complex testing, method or equipment validation or higher level roles involving supervision.

Definition of Technician

NPAAC defines a technician as a person with one of the following qualifications:

(i) associate degree or diploma as per Australian Qualifications Framework with subjects relevant to pathology or laboratory operations awarded by a recognised Australian TAFE or RTO

(ii) qualification with subjects relevant to the field of pathology awarded by an overseas tertiary institution after not less than two years full-time study or an equivalent period of part-time study and where the qualification is recognised as equivalent to a diploma by the Australian Institute of Medical Scientists according to their authority approved by the Australian Education International-National Office of Overseas Skills Recognition

with appropriate training and certified competencies to perform the functions required and who is authorised to perform this function by the Laboratory Director.

Definition of Scientist

If the scientific and, consequently, laboratory technical roles are being redefined, it is timely to review the definition of a Medical Scientist (Pathology).

Review of requirements by societies and associations show diversity in requirements for a scientist. These various requirements are detailed below:

Australian Institute of Medical Scientists (AIMS) defines a scientist as:

> one who has completed an AIMS accredited degree or an acceptable science degree (which includes full units of human anatomy, human physiology, chemistry, biochemistry, immunology, general microbiology, general pathology, human molecular biology and at least two of the subjects clinical chemistry, haematology, medical microbiology, transfusion science and histopathology/diagnostic cytology).

To be a Graduate Member of AIMS, the individual needs to hold an AIMS accredited qualification.

To be a Professional Member of AIMS the individual needs to hold one of the above qualifications and a minimum of two years post graduate professional medical laboratory experience in an approved diagnostic medical laboratory, OR be a graduate of a relevant science degree course that meets AIMS requirements in the subjects studied and have completed two years postgraduate professional experience in a diagnostic medical laboratory and have successfully completed the AIMS Professional Examination.

According to the ***Australian Society of Cytology*** (ASC), NPAAC requirements for Gynaecological (cervical) Cytology 2006 state (footnote 2):

> "Appropriate training for scientists is defined as having a relevant degree in science or applied science together with a minimum of two years full-time training/experience in NATA/RCPA accredited laboratory for gynaecological cytology. A senior cytotechnologist is

a person having the equivalent of five full-time years experience in cytology and holding a qualification which designates competence in cytology."

Human Genetics Society of Australasia (HGSA) requires ordinary Members shall be such persons who:

(i) Hold a relevant degree or professional qualification from an Australasian university or other institution, or an equivalent degree or qualification from a non-Australasian country; and

(ii) (a) Whose primary vocation involves or has involved, significant clinical, laboratory, administrative, or other professional responsibility in the clinical care, diagnosis, or management of individuals or families with genetic or developmental conditions; or

(b) Whose primary vocation is, or has been, research, education or administration related to Human Genetics

Associate members of ***Australasian Association of Clinical Biochemists*** (AACB) must possess a degree from an approved University or an equivalent tertiary qualification.

Australian Society of Microbiology (ASM) professional class of membership (Member of the Australian Society for Microbiology) requires:

(i) Completion of requirements of an academic qualification in microbiology at degree level or alternative qualifications acceptable to National Council; AND
(ii) Completion of two years of post graduate full-time employment, or its equivalent, as a practising microbiologist

Definition of Senior Scientist

NPAAC 'Requirements for the Supervision of Pathology Laboratories' defines a senior scientist as a *"scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications:*

(a) a Doctorate of Philosophy in a subject relevant to the field of pathology
(b) a Fellowship of the Australasian Association of Clinical Biochemists
(c) a Fellowship of the Australian Institute of Medical Scientists
(d) a Fellowship of the Australian Society for Microbiology (medical/clinical microbiology)
(e) a Fellowship of the Human Genetics Society of Australasia
(f) a qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the Health Insurance Act 1973, to be equivalent to a qualification referred to in paragraph (a), (b), (c), (d), or (e) of this definition."

It is envisaged that a senior scientist will play a senior role in the functioning of a pathology laboratory and will be involved in tasks such as creation of assays and research and development in both analytical and clinical sense.

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Appendix 1:

Scope of Practice

	Laboratory Assistant and above	Technician and above	Scientist and above	Senior Scientist	
Technical Skills * Collection, preparation and analysis of clinical material					
1.1 Ensure the appropriateness of sample collection procedures	Understands correct identification and labelling requirements for patient specimens	Aware of collection instructions for test procedure/s and correct specimen/s required for testing	Understands transport requirements for test and notifies appropriate staff if this is exceeded and/or results are compromised		
1.2 Ensure the appropriateness of specimen reception procedures	Determines acceptability of samples within established guidelines	Aware of requirements to match specimen and documentation upon receipt in laboratory	Notifies appropriate staff if patient identification error is observed or specimen is sub-optimal		

1.3 Evaluate specimen suitability prior to analysis	Determines acceptability of samples using established protocols and guidelines									
1.4 Determine the priority of laboratory requests (triage) to effectively manage service requirements	Prioritises assignment of test requests according to established guidelines	Coordinates general workflow and reorganises to suit changes in priority	Ensures quality and timeliness of patient test results by investigating problems involving specimen collection, result reporting and turnaround time							
1.5 Process specimen utilising appropriate techniques	Prepares specimens for analysis	Performs standard laboratory techniques under supervision	Operates laboratory instruments appropriate to role	Performs quality control procedures using established protocols	Troubleshoots instrument problems using established procedures	Performs preventative and corrective maintenance and repairs on laboratory equipment appropriate to role	Performs some non-automated and automated laboratory techniques appropriate to role	Performs some non-automated and specialised laboratory procedures	Recognises appropriate and inappropriate selection of all lab tests	Determines when "backup" methods must be initiated

1.6 Read and validate results	Where necessary, enters results and quality control data according to laboratory protocols	Performs preliminary evaluation of quality control and refers data to scientific staff	Where necessary, records observations and details according to regulatory requirements	Evaluates quality control measures and institutes appropriate corrective action within established guidelines	Uses statistical methods to research and assess laboratory testing	Evaluates and calculates quality control statistics to assess accuracy, reproducibility and validity of current laboratory methods	
Knowledge Base * Correlation and validation of results of investigations using knowledge of method(s) including analytical principles and clinical information							
2.1 Assess validity of data / results against possible range of outcomes	Recognises and refers implausible results	Recognises and refers abnormal results	Understands the basic physiology behind laboratory results	Identifies technical, instrumental, and/or physiologic causes of unexpected test results	Develops solutions to problems based on knowledge, patient diagnosis and instrument performance	Demonstrates high level of clinical and scientific expertise	
2.2 Perform validation of results	Evaluates and interprets test results within position requirements	Reports abnormal results within position requirements and seeks advice when necessary	Has knowledge of the theory of laboratory procedures				

2.3 Make decisions about reporting results, repeating procedures, consulting senior staff and carrying out further tests within established guidelines	Recognises and refers results when necessary and follows documented procedure in dealing with rejected results	Recognises and refers questions and/or problems to appropriate personnel	Refers requests for special and unusual tests	Differentiates technical, instrumental and/or physiologic causes for unexpected test results	Recognises appropriate and inappropriate selection of basic laboratory testing	Correlates abnormal laboratory data with pathologic states to determine validity and/or whether follow-up tests should be done	Integrates and relates lab data generated by various lab sections in making judgements regarding possible discrepancies	
Analytical / Decision Making * Interpretation, reporting and issue of laboratory results								
3.1 Verify report(s) with sample identification	Ensures patient identification is traceable at all steps of testing process	Deals with inconsistency in sample identification appropriately	Reports test results appropriate to role					
3.2 Use the administrative systems in place to communicate the results	Observes principles of data security / patient confidentiality	Follows procedures to ensure communication of results occurs in timely manner and this process is documented	Identifies and follows up overdue results					

3.3 Ensure that results with important diagnostic or treatment implications are communicated as per established protocols	Recognises significant results and alerts appropriate staff	Performs analytical and decision-making functions under supervision	Ensures reference intervals and/or reported comments on results are communicated where necessary and this is documented according to procedures	Ensures accurate advice is communicated where necessary and this is documented according to procedures	Works with Pathologists to establish critical-level values and develop acceptable criteria	Interacts with other health care workers to solve problems and interpret patient lab results within the framework of medical science	Informs physicians concerning details and limitations of lab procedures	Creates an evidence base for use by clinicians for the benefit of patients	
3.4 Ensure appropriate storage and disposal of data and reports	Ensures results are recorded according to regulatory requirements	Ensures results and/or reports are stored according to regulatory requirements	Ensures reports are disposed according to regulatory requirements and ensuring privacy and confidentiality is maintained	Analyses laboratory computer applications to manage data					
Resource Maintenance * Maintenance of documentation, equipment, resources and stock									
4.1 Coordinate supplies of stocks and reagents	Maintains inventory and supplies	Ensures stock received is transported and subsequently stored according to manufacturers specifications	Disposes expired or dangerous goods according to regulations	Ensures quarantine of expired or contaminated stock to prevent inadvertent use	Maintains adequate stocks of blood and blood products according to pre-determined stock levels and defers any issues with supply to senior staff member as required	Determines quantities of blood and blood products to be held by laboratory			

4.2 Participate in maintenance of the laboratory and equipment	Ensures proper functioning of laboratory equipment	Performs preventative and corrective maintenance and repairs on basic laboratory equipment	Calibrates laboratory instruments within requirements of position to ensure accuracy	Ensures safety protocols for equipment are maintained and risk assessments are performed if deviation to normal safety protocols				
4.3 Participate in preparation and revision of manuals and protocols	Consults with relevant personnel regarding need for change to documentation	Maintains records / documentation and monitors for any updates	Follows relevant guidelines for method / manual content	Appropriately communicates changes to all relevant staff	Writes procedures according to prescribed format	Creates analytically valid and traceable routine assays, underpinned by reference materials and methods in order to measure entities appropriately	Approves new methods as fit for use	
4.4 Ensure appropriate resources are available to the laboratory	Suggests cost effective laboratory procedures or protocol	Communicates requirements for laboratory resources to appropriate personnel	Involved in appropriate utilisation of human and technical resources, including position descriptions					

Safety

* Maintenance and promotion of safe working practices

5.1 Prepare and store reagents and solutions	Prepares, labels, handles and stores reagents according to requirements	Maintains inventory of hazardous reagents including MSDS and reviews periodically to ensure substances no longer in use are discarded appropriately					
5.2 Identify and respond to unsafe work practices and breaches of regulations	Complies with and promotes safety guidelines	Ensures procedures do not contain unsafe practice and notifies appropriate personnel with concerns or improvement suggestions					
5.3 Ensure correct procedures are followed for acquisition, collection, storage, transportation and disposal of biological, toxic and radioactive wastes	Ensures receipt, despatch from laboratory and disposal of biological, toxic or radioactive substances is according to guidelines	Ensures protocols for handling of dealing with spills of biological, toxic or radioactive substances are followed	Adheres to appropriate safety regulations and is responsible to community and environment when handling and/or disposing of hazardous substances	Holds appropriate licence for handling radioactive substances	Enforces safety regulations	Develops safety and waste management procedures	

5.4 Respond appropriately to emergency situations	Familiar with safety documentation and use of safety equipment	Documents safety related incidents according to protocol	Aware of hazards caused by interaction of some substances		
Professional Development * Professional accountability and participation in continuing professional development					
6.1 Establish and communicate personal goals in professional development	Displays interest and participates in departmental education commensurate with level of training	Responsible for own professional development	Identifies and discusses goals for professional development	Assists with professional development of staff	
6.2 Maintain and update scientific / technical knowledge and skills	Updates knowledge by attending relevant meetings, reviewing scientific and technical literature and case studies				

6.3 Develop skills relevant to the enhancement of professional growth	Volunteers for additional duties and shows initiative in suggesting improvements	Demonstrates understanding of laboratory operations and place of laboratories in health care	Develops additional skills by participating in relevant activities or attending approved courses	Develops and utilises research skills	Researches and develops the field of analysis both analytically and clinically	
6.4 Recognise own abilities and level of professional competence	Identifies unprofessional conduct and reports serious breaches to appropriate authorities	Intervenes, where applicable, to ensure rights and/or safety of person/s in the workplace	Undertakes work and gives guidance and advice within bounds of one's abilities, qualifications and training	Consults with senior staff when necessary	Sets an example to others in the workplace	
6.5 Comply with profession's code of ethics	Maintains ethical standards and displays professional conduct in a non-discriminatory manner	Maintains confidentiality and professional competence	Exercises professional judgement, skill and care in decisions made regarding patients and others			

Accountability

* Responsibility for Medical Science practice including test selection, development and use of laboratory investigations

7.1 Accept responsibility for own actions / omissions	Able to make appropriate decisions commensurate with level of experience and/or job description	Delegates tasks (or enlists help of others) and ensures appropriate completion of these, commensurate with role and ability					
7.2 Make independent, professional judgements	Applies step-by-step thinking, problem solving and critical thinking patterns and is aware of implications associated with outcomes	Performs analytical and decision making functions without supervision	Supervises laboratory personnel as assigned	Contributes to resolution of conflicting decisions / interpretations within the laboratory	Demonstrates responsibility and accountability for management and planning of services and/or departments	Responsible for or contributes to strategic direction of laboratory	
7.3 Demonstrate knowledge of contemporary ethical issues impinging on Medical Science	Considers ethics within laboratory environment relating to data, events or business relationships	Refers ethical problems in the workplace to a higher authority	Respects the rights of individuals or groups in the workplace				

7.4 Demonstrate knowledge of new tests and their potential in the laboratory	Performs new procedures as directed	Evaluates and validates new methodologies	Possesses scientific knowledge to evaluate clinical laboratory technology	Reviews current literature relating to new or improved procedures and makes recommendations for adoption where appropriate	Develops and implements new tests as required	Identifies tests / parameters which help diagnose, screen and monitor treatment	Demonstrates innovation and highly developed and specialised skills	
Communication * Liaison with health workers and others to continuously improve the service								
8.1 Participate in quality improvement activities	Documents issues and refers these to senior staff	Performs quality assurance relevant to laboratory role	Monitors quality assurance	Identifies and suggests standards of practice	Continuously improve quality to meet goals	Audits clinical use, general guidelines and promulgates best practice		
8.2 Continually review laboratory processes and testing to streamline, minimise waste and increase efficiency	Suggests cost effective laboratory procedures or protocol	Implements changes in response to technology and laboratory procedures						

8.3 Establish and maintain relationships with suppliers	Assists in establishing and maintaining appropriate communication with internal and external suppliers	Assists in establishing service level for suppliers and documents and refers any failure of this to senior staff	
8.4 Establish and maintain relationships with service users	Communicates and maintains confidentiality in relation to service delivery	Demonstrates awareness of key performance indicators to ensure laboratory meets clients needs	
Education / Training * Participation in education and training of health workers and others			
9.1 Research, prepare and deliver appropriate presentations to peers in-house or externally	Prepares and delivers training and/or presentations relevant to position as required		

9.2 Participate in interdepartmental and other meetings	Prepares and presents continuing education lectures and conferences for personnel					
9.3 Where appropriate, provide instruction on collection, testing of specimens, interpretation and significance of results and service delivery	Responds to technical questions consistent with level of training, knowledge and/or qualifications	Provides instruction on collection and/or testing of specimens commensurate with experience and qualifications	Provides advice on interpretation and significance of results, giving consideration to clinical information and limitations of test			
9.4 Train personnel in the operation of instruments and equipment, the performance of methods and quality control procedures, patient confidentiality, and the observation of safety measures	Trains staff commensurate with experience and qualifications	Teaches theory and procedures using educational methodology and establishes feedback to monitor effectiveness of training	Instructs personnel in work group on new methods / instruments	Trains laboratory personnel in new technology and laboratory procedures	Instructs patients, new technicians, medical students, residents and peers regarding laboratory testing as required	

Research and Development * Contribution to advancement of knowledge and improvement of laboratory practice						
10.1 Contribute to planning and design of research and development projects	Identifies issues and communicates research idea to appropriate personnel	Assists with design of the project within position requirements	Accesses appropriate information related to the project	Understands ethics and protocols associated with research	May initiate or lead formal research projects	
10.2 Follow research / development protocol	Assesses and assembles resources for project	Follows procedures and monitors and documents outcomes				

10.3 Evaluate results and the need for further experimental work	Assists in evaluation and selection of new equipment	Evaluates and validates new methodologies	Collects, analyses data and contributes to interpretation of results	Assists in determining requirements for further research in consultation with appropriate personnel	
10.4 Prepare and deliver report	Prepares and reviews reports (written, verbal, journal) and submits for peer review				