**National Certification Scheme for the Medical Laboratory Scientific Workforce**

**Final Report**

May, 2019



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# Acronyms and abbreviations

AACB Australasian Association of Clinical Biochemists

ACS Australasian Cytometry Society

AHPRA Australian Health Professions Regulatory Authority

AIMS Australian Institute of Medical Scientists

ANZSBT Australia and New Zealand Society for Blood Transfusion

APRN Advanced Practice Registered Nurses

AQF Australian Qualification Framework

ASC Australian Society of Cytology

ASCIA Australian Society of Immunology and Allergy

CME Continuing Medical Education

CPD Continuing Professional Development

FSA Fertility Society of Australia

HCA Human Capital Alliance

HGSA Human Genetics Society of Australasia

NATA National Association of Testing Authorities

NCSBN National Council of State Boards of Nursing

NPAAC National Pathology Accreditation Advisory Committee

PAC Pathology Associations Council

QA Quality assurance

QC Quality control

QI & CPD Quality Improvement and Continuing Professional Development

QUPP Quality Use of Pathology Program

RCPA Royal College of Pathologists of Australasia

RTAC Reproductive Technology Accreditation Committee

SIRT Scientists in Reproductive Technologies

THANZ Thrombosis and Haemostasis Society of Australia and New Zealand

VET Vocational Education and Training

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# Executive Summary

## Process

In July 2017, a process to gauge the enthusiasm amongst relevant stakeholders for the development and implementation of a scheme to certify the competence of sections of the medical laboratory scientific workforce commenced. Almost 2 years later, and after countless informal and structured (interviews, workshops, meetings, Delphi conferencing) consultations, a Certification Scheme has been detailed and is ready to be implemented.

In the process, many very relevant stakeholders with a keen interest, despite holding sometimes disparate and even conflicting perspectives, have fashioned an agreed common path forward. The agreed approach is based on a shared desire to provide leadership in promoting the ongoing development of the competence, professionalism and recognition of the medical scientific workforce for them to continue to deliver safe and high-quality services to consumers. The significant support of the Commonwealth Department of Health in enabling this process to occur needs to be fully acknowledged.

## Recommended model

Throughout the consultation process, an agreed position on several key Certification Scheme elements was sought. These are elements that a literature review and case study analysis found to be critical to any certification scheme structure and operation, as follows:

* Accountability and governance arrangements
* Requirements of participation in the Scheme
* Levels of workforce to be included in certification
* Entry requirements to apply for certification
* The competency basis / standards for certification
* Methods of competency assessment
* Recertification and maintenance of certification
* Sanctions for not staying competent or breaching conduct codes
* Cost of participation.

For all these identified elements, a position of consensus was able to be closely approached, with the Delphi Conference delivering a high proportion of conference respondents indicating that they ‘completely’ or ‘mostly’ agree with the final stated position, ranging from a low of 87% to 100%.

## Implementation

An Implementation Plan has been developed which provides the final position reached for each of the Scheme elements and outlines the steps that now need to be taken to bring the Certification Scheme to fruition. In some cases, some more detailed work remains to be completed on the elements before the Scheme can commence, but this quite appropriately will now be the task of the Scheme’s governance body which will be made up of representatives from ten or more relevant professional associations.

The Implementation Plan is divided into three distinct phases, as recommended by the stakeholders and according to key assumptions that have been adopted to guide the pace of implementation for the proposed Scheme, in which participation will be voluntary at the outset.

These three phases are:

**Phase 1: May to September 2019** – during this phase, the Scheme’s governance arrangements will be put in place and mechanisms developed to promote the Scheme and support receipt of certification applications. This will be a brief but crucial and challenging period, likely to be undertaken without a dedicated administrative resource and with limited income to draw from. Key actions include:

* establishing a legally structured governance arrangement for the Scheme (Company Limited by Guarantee), guided by the draft Constitution that is included with this plan
* nomination of inaugural Board of Directors by the Scheme member organisations
* contracting for the design and development of a website for the Scheme promotion and online interactions with prospective certification applicants
* development of mechanisms to receive and transact applications for certification
* finalisation of positions on entry requirements, acceptable courses, competency assessment, fees, etc. as required.

**Phase 2: October 2019 to June 2020** – during this phase, an administrative infrastructure will be put in place, staff will be recruited, and the mechanisms developed in Phase 1 will be trialled so that design flaws can be identified and fixed prior to the formal launch of the Scheme on 1 July 2020. There is an expected income flow to commence during this period because of early entry arrangements to the Scheme so financial pressures will be less prescient but decisions will need to be made during this phase that will impact for some years. Key actions include:

* recruiting and employing a Scheme Registrar and appropriate administrative support
* promoting the Scheme to the workforce through a well-crafted communication strategy
* finalising the Scheme infrastructure in preparation for trialling the administrative and assessment mechanisms of the Scheme
* take applications (and discounted fees) from a sufficient number of ‘early adopter’ / ‘beta testers’ in order to properly trial the Scheme’s infrastructure
* Identify and solve any problems that may emerge during this testing phase.

**Phase 3: July 2020 to October 2023** – this phase will encompass the first three years of the full functioning of the Certification Scheme. In some ways, it will be a period of consolidation, but at the same time it will include preparing for more rigorous certification requirements and laying the groundwork for future expansion – for example, in types of workforce, product development and relationships with key external stakeholders (including regulatory bodies, employers, governments). Key actions are likely to include:

* preparing tools and materials for more rigorous certification requirements
* consolidating relationships with non-member stakeholders but especially regulatory bodies
* developing relationships with other certifying bodies
* developing additional capacity for Scheme expansion
* evaluating the initial years of implementation and learnings to apply those lessons to the next cycle of recertification and planned expansion of the Scheme.

## Project assessment

Against a background of past let-downs and fragmentation in the quest for certification / registration of the medical scientific workforce, this project proved a considerable success. With the preparation of an Implementation Plan, which will remain a working document for further refinement by those who have already committed to taking this plan to fruition, a certification scheme for the medical laboratory scientific workforce is tangibly close and within the grasp of an eager profession.

That such a strong consensus around the proposed scheme, its governance arrangements, its financial mechanisms, its implementation processes, has been garnered is a testament to the willingness of many stakeholders to subjugate some of their own interests in search of a commonly desired goal.

If the Scheme proves its worth to the profession itself and to employers, regulators and consumers it is likely to become a benchmark in the health workforce market for assuring competent professional practice.

# Background and project rationale

## Background

Improving quality standards of the pathology workforce has been explored and realised through various means. Previous investment under the QUPP on pathology scientific workforce career pathways identified ongoing professional development, primarily on-the-job, as a key to genuine competence enhancement of scientists and the Vocational Education and Training (VET) trained (technical support staff) workforce. Appropriate recognition of enhanced competence, in the form of certification, was identified as important to motivate a desire for enhanced competence.

In terms of what already exists, it is a requirement of the National Pathology Accreditation Advisory Committee (NPAAC) standards to assess staff competence at regular intervals. Part of the joint National Association of Testing Authorities and the Royal College of Pathologists of Australasia accreditation assessment process is to assess staff competence through peer-assessments and evidence of organisation systems to maintain staff competence. A well-defined mechanism is yet to be realised for more directly and objectively assessing and monitoring professional competence of the pathology scientist and technician workforce that provides assurance of the ongoing capability of key staff.

## History of the pursuit of certification

The need for enhanced regulation of scientist competence was first raised through a formal application for registration of medical scientists to the Australian Government in May 2008. Unfortunately, a subsequent application to the Australian Health Practitioner Regulation Agency (AHPRA, which covers all Australian jurisdictions) for inclusion of medical scientists in the national accreditation regulatory framework was rejected. The key reason for this professional group not being considered a high enough potential risk to warrant mandatory registration is that there is a national pathology accreditation program for pathology laboratories and Fellows of the Royal College of Pathologists Australasia (RCPA), who currently hold full clinical responsibility for pathology service provision and are already covered by registration. A recommendation was made by AHPRA at that time for the medical science profession to develop a system of **self-regulation**.

This objective has been much discussed in the intervening almost 10 years, but through the lack of a coherent and compelling system design, which addresses all stakeholder concerns, and available resources, the idea has failed to progress. Accordingly, the scientific workforce in pathology is one of the few remaining professional health workforce groups that are not subject to either mandatory regulation of standards for entry to the profession or for maintenance of those standards over time.

Several the other health professions similarly placed have initiated self-regulation[[1]](#footnote-2), in the form of certification of their membership for entry and (to a greater or lesser extent) maintenance of professional competence. Indeed, Medical scientists are currently one of the few remaining Australian healthcare professions that do not have certification schemes to recognise professional skills. A list of current health professions either regulated or self-regulated in Australia is provided at Appendix A.

The ambitions of the profession regarding certification were consistent with the desire of the Department of Health to reinforce quality processes based on a more structured and reliable means of ensuring workforce competence. While not appropriate for the Commonwealth to underwrite a particular mechanism to ensure workforce competence standards, the Department through a Quality Use of Pathology Program (QUPP) grant was willing to fund this project to examine the feasibility and nature of a Certification Scheme. It needs to be acknowledged that the Scheme that this project makes tangibly close to fruition would almost certainly never have eventuated without the Commonwealth’s investment.

## Aim of the project

The broad aim of the project was to *develop and implement an objective, transparent and effective national model of professional certification for pathology laboratory scientist competence, and to provide an objective indication of readiness for different levels of laboratory practice[[2]](#footnote-3)*.

Within the overall objective of defining an agreed and sustainable certification model for the Australian medical scientist profession, the more specific objectives of this project were to:

1. provide stakeholders with a strong evidence base for assessing relevant models for professional certification with the aim of developing a professional certification model for the Australian scientific workforce (the Discussion Paper)
2. engage the relevant scientific professional organisations in effective collaboration (stakeholder consultations and two Stakeholder Workshops)
3. craft initial consensus on a possible way forward among all pathology laboratory stakeholders on a professional certification model that is objective, evidence-based and sustainable (this Position Paper)
4. identify and address any outstanding stakeholder reservations in relation to the acceptance of a certification model
5. provide a clear map to future action through an implementation plan.

## The case for certification

This project builds on previous investment under the Quality Use of Pathology Program (QUPP) on pathology scientific workforce career pathways[[3]](#footnote-4) (and developments that have occurred since, utilising the resource material developed). The Career Pathways project identified elements of the career pathway where ongoing professional development, primarily on-the-job, leads to genuine competence enhancement of scientists and the Vocational Education and Training (VET) trained (technical support staff) workforce, and that increase in capability required appropriate recognition.

More generally, there has been an increasing focus on risk identification and management and associated improved outcomes for consumers, which is being pursued in the continuing development of the national pathology quality standards that are developed and reviewed by the National Pathology Accreditation Advisory Council (NPAAC). NPAAC have adopted a risk-based approach to patient safety which is reflected in the latest *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories* and *Requirements for Medical Pathology Services documents*. Accordingly, it is timely to consider the structures that support the recognition of competence and responsibilities of Clinical Scientists and Scientists.

Within this context, a better articulated mechanism for assessing and monitoring the professional competence of the pathology scientist workforce would provide a more efficient and accessible benchmark to ensure the ongoing capability of key staff in Australian pathology laboratories to conduct and manage pathology diagnostic tests. As Howanitz et al. (2000) have noted:

*“A capable laboratory must have capable employees. In line with the weakest link principle, the laboratory as a whole or any section may be unable to provide high-quality work at all times if any individual is not competent to perform assigned tasks, has never received adequate training in performing all tasks properly, or does not appreciate how a procedure should be performed. Eventually the employee’s lack of competence will cause mishandled test requests, lost specimens, or erroneous results. Any of these problems potentially affect adversely patients’ medical outcomes.”*

As part of the laboratory accreditation process currently it is a requirement that all laboratory staff have assessment of competence at regular intervals. Vervaart (2016) notes the NPAAC accreditation requirements cover a wide range of quality-related elements of laboratory practice, including some standards from the International Organization for Standardisation (in particular AS ISO 15189: Medical laboratories – Requirements for quality and competence). All laboratories seeking accreditation under the joint National Association of Testing Authorities and Royal College of Pathologists of Australasia (NATA/RCPA) assessment scheme are assessed against the NPAAC requirements, with the aid of the NATA Medical Testing ISO 15189 Field Application Document (FAD) which provides interpretative criteria and recommendations for the application of AS ISO 15189 and the NPAAC Requirements.

Regarding worker competence, section 5.1.6 of the ISO 15189 Standard relates to Competency Assessment and states that:

*“Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria … Reassessment shall take place at regular intervals. Retraining shall occur when necessary.”*

Further, the NPAAC Requirements for Medical Laboratory Services states that:

*“S4.1 There must be sufficient medical, scientific, technical and support staff who have the qualifications, training and competence to provide Medical Pathology Services consistent with the Laboratory’s Quality System.”*

And, perhaps more to the point in reference to a possible scheme to certify competence, these requirements include:

*“C4.1(i) There must be documentation demonstrating that the education, training and competence of individual staff members and their trainers is appropriate and adequate for the tests and procedures being performed”* (emphasis added by authors).

External certification with appropriate regular competence assessment would introduce a more consistent and objective approach to this risk management process. As part of the risk-based approach to pathology accreditation, there is more consideration of any potential risk factors, including individuals’ competence and the need to increasingly look for ways to target specific risk factors where the evidence supports further attention.

## Certification logic

The pursuit of certification is an attempt to primarily establish and recognise minimum standards of worker competence (certification) that are aimed at minimising professional practice error, particularly error based on any competence deficit of workers. A certification model for the scientific workforce would address the QUPP objective related to Quality Pathology Practice, which is:

“*To support professional practice standards that meet consumer and referrer needs and provide evidence-based, best practice, quality-assured services that are safe, cost effective and efficient*”.

The ‘logic’ between certification and the desired outcomes of QUPP Objective (3) and (1) is developed in Figure 1.

The logic also strongly suggests other potential human resource management benefits from certification (especially if competency based) including for recruitment, promotion, training efficiency and even workforce planning.

**Clear & accurate assessment of scientist (technician) level of skill / competence**

1. Appropriate & effective allocation of work to individual workers according to their level of competence and therefore risk mitigation limits (including to scientists and technicians working in less supervised areas of practice like Category B laboratories)

***Provision of evidence-based, best practice, quality-assured services that are safe, cost effective and efficient***

2. Clear understanding of existing workforce capacity (within a laboratory, organisation, jurisdiction) to undertake all forms of laboratory work with minimum error

2A. Efficient identification of areas of workforce / worker skills and competence that need to be **developed** to reduce if not eliminate risks of error

2B. Clear specific-identification of types of competencies that employers need to **recruit** to obtain a sufficiently competent workforce to minimise risk of errors

2C. Ready identification of correct workers (those most suitably competent) to **promote** to supervisory or technically demanding roles

Figure 1: Proposed logic between proposed intervention and outcomes

# Scope of the project

## Workforce coverage

### NPAAC role definitions

The only role definitions that are prescribed nationally for the scientific workforce of pathology laboratories are those that are set down in the standards and associated regulations associated with the national pathology accreditation regulatory framework. These standards are recommended to the Australian government by the NPAAC. Specifically, these definitions are associated with varying levels of supervision capability and are designed to set parameters around the safe delegation of supervision responsibilities within pathology[[4]](#footnote-5) laboratories.

The current NPAAC definitions (NPAAC Requirements for Supervision, 2007) are as follows:

**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.

**Scientist** means a person who possesses one of the following qualifications:

(a) a degree in science or applied science with subjects relevant to the field of pathology awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a professional class of membership of the AACB, Australian Institute of Medical Scientists, Australian Society for Microbiology, Australian Society of Cytology, Human Genetics Society of Australasia

(b) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973

(c) 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) or (b) of this definition.

**Senior scientist** means 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 Doctor of Philosophy in a subject relevant to the field of pathology

(b) a Fellowship of the AACB

(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 adopt more supervision responsibilities and oversight 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.

### ANZSCO role definitions

There are relevant definitions of laboratory staff and associated roles in the Australian & New Zealand Standard Classification of Occupations (ANZSCO), as shown in Box A below, and these definitions do provide more detail on the role scope.

**BOX A**

MEDICAL LABORATORY SCIENTISTS (ANZSCO Code 234611) conduct medical laboratory tests to assist in the diagnosis, treatment and prevention of disease. Tasks Include:

* preparing tissue sections for microscopic examination
* examining and analysing samples to study the effects of microbial infections
* analysing samples of body tissue and fluids to develop techniques to aid in the diagnosis and treatment of diseases
* advising Medical Practitioners on the interpretation of tests and methods for use in the diagnosis and treatment of disease
* setting up the steps and rules of laboratory medical testing
* operating and maintaining laboratory equipment
* maintaining laboratory quality assurance and safety standards
* preparing scientific papers and reports.

MEDICAL LABORATORY TECHNICIANS (ANZSCO Code 311213) perform routine medical laboratory tests and operate diagnostic laboratory equipment under the supervision of Medical Laboratory Scientists and Pathologists. They may also be titled ‘Medical Laboratory Technical Officer’.

The findings of a study of Medical Scientist career pathways (Ridoutt et al., 2009) indicated that not all the scientific profession is entirely comfortable with the ANZSCO definitions, or particularly how they are applied to counting scientists and technicians in the workforce at each Population Census. This is reportedly largely because of the unclear boundaries between professionals working in pathology medical laboratories and those working in similar settings but with different roles (e.g. medical research, pharmaceutical development, medical product industry etc.). The ANZSCO definitions are therefore included here for completeness and to indicate the currently available mechanism for collecting potentially relevant national data.

### Sub-specialty scope of practice

The competency framework outlined above is also intended to be appropriately applied to the particular scientific discipline context in which each practitioner requires competency. This includes (but may not be limited to) the following:

1. Microbiology
2. Biochemistry
3. Cytology
4. Haematology
5. Blood transfusion
6. Genetic science
7. Immunology
8. Virology
9. Histology
10. Fertility science
11. Flow cytometry.

At present, the professional recognition and continuing professional development benchmarking arrangements for these sub-specialty areas of practice are covered by mechanisms that have been put in place by specific professional associations. Most (but not all, e.g. AIMS) limit their focus to specific disciplines and participation in these programs is voluntary. The extent of membership coverage of the scientific workforce is reportedly variable both within and between professional associations. Some sub-specialties, such as cytology and blood transfusion, are subject to a higher level of regulation of their professional activities, largely due to the evidence base in relation to risk-associated with this area of practice.

As indicated in the Scope section above, this type of recognition scheme is offered by AIMS, the AACB, the Australian Society of Cytology, and the Australian Society of Microbiology. Recognition status from these organisations is offered variously, ranging from entry-level to mid-career and senior scientist recognition arrangements. The RCPA also offers an assessment and recognition process for senior scientists under the auspices of their Faculty of Science. This professional qualification can be undertaken in a wide range of disciplines and is a specifically recognised pathway by some other sub-specialty professional groups, including the Human Genetics Society of Australasia, the Fertility Society of Australia and the Australasian Society for Clinical Immunology and Allergies, in addition to other levels of discipline-specific recognition/membership eligibility.

A further group of associations, such as the Australian and New Zealand Society for Blood Transfusion (ANZSBT), are very active in organising and promoting discipline-specific continuing professional education opportunities and others, such as the Thrombosis and Haemostasis Society of Australia and New Zealand, the Endocrine Society of Australasia and the Australian Cytology Society, provide an active hub for networking and professional development. There is also some inter-discipline cooperation, particularly in relation to continuing professional development (CPD), where a common platform for the provision and monitoring of CPD is shared (e.g. utilisation of the Australasian Professional Acknowledgement of Continuing Education program or APACE CPD mechanism operated by AIMS).

## Different quality assurance approaches

The quality assurance arrangements and public safety management frameworks that address health professionals are quite diverse, both within and outside the Australian health care context and across the spread of occupations. They encompass (but may not be limited to) these key types of management approaches:

* formal mandatory registration requirements (regulation-linked) (e.g. as required for pathologists as medical specialists)
* licensing requirements (e.g. for use of radiation)
* formalised but voluntary whole of profession requirements that largely mimic registration arrangements (e.g. professions participating in NASRHP)
* unregulated but widely accepted minimum education and/or training standards (e.g. employers will not normally engage a speech pathologist without evidence that an applicant is eligible for membership of the Speech Pathologists Association of Australia).

These quality assurance arrangements may also be undertaken and/or required in combination (e.g. medical radiation practitioners must be registered and hold the relevant radiation licence/s).

### Regulatory approach

Regulated health professions in Australia are governed by the National Registration and Accreditation Scheme (NRAS) that was implemented in 2010 and is overseen by the AHPRA. The key aims for this scheme are outlined in Figure 2 below.

Figure 2 Objectives of the NRAS

The National Law s3(2) identifies six objectives for the Scheme as a whole:

1. *to provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered; and*
2. *to facilitate workforce mobility across Australia by reducing the administrative burden for health practitioners wishing to move between participating jurisdictions or to practise in more than one participating jurisdiction; and*
3. *to facilitate the provision of high quality education and training of health practitioners; and*
4. *to facilitate the rigorous and responsive assessment of overseas-trained health practitioners; and*
5. *to facilitate access to services provided by health practitioners in accordance with the public interest; and*
6. *to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.*

There are currently 15 regulated health professions in Australia, each governed by a profession-specific board. However, in addition to any specific requirements each board may set in relation to the competency of its individual profession, the NRAS scheme requires that all professions meet core requirements for the following standard topics:

* criminal history check
* English language skills
* CPD
* currency of practice
* professional indemnity insurance arrangements.

In addition to these threshold requirements, each of the 15 regulated health professions is required to develop its own professional competency framework which defines the capabilities and outcomes expected of a qualified health practitioner in that specific field. According to the discussion paper released by the Council of Australian Governments Health Council (COAG)’s independent review of accreditation systems in February (AHMAC, 2017), each professional competency framework under the NRAS currently differs across its domains (or fields or elements) that define a competent health practitioner. This does not, however, mean that there are no common themes between the professional standards sets (ALTC, 2011).

The current approach to setting of professional education and practitioner standards, though, has been queried by the Productivity Commission, which in its 2005 report proposed a separation between regulation of education requirements and the assessment and maintenance of standards for individual health practitioners:

*“...it would be good regulatory practice to separate the setting and verification of standards at the education and training institutional level from the application and maintenance of standards in relation to individual practitioners. Further, the Commission believes it is possible to establish two separate boards — accreditation and registration — on an ‘impartial and independent’ basis.*

*To avoid conflicts of interest, where there is a need for formal representation of specific stakeholders in strategic decision making, stakeholder engagement mechanisms such as an advisory or consultative committee should be established, rather than making those stakeholders members of the regulator’s governing body.”*

This concern has been repeated in the COAG review’s findings and flagged for further consideration.

### Self-regulation approach

The National Alliance of Self-Regulating Health Professions (NASRHP) is a body that was formed in 2008 (informally at first) to provide a forum and a voice for those Australian health professions that lay outside the intended initial scope of the NRAS but wished to have their profession’s desire for quality practice recognised more formally. Australian peak bodies of self-regulating allied health professions wishing to join NASRHP must meet benchmark standards for regulation and accreditation of practitioners within that profession. NASRHP does not provide individual certification for practitioners.

NASRHP standards have been closely modelled on AHPRA standards and are composed of the following 11 standards (including the five standards that are mandatory under the NRAS scheme, as outlined above):

1. Scope (areas) of practice
2. Code of ethics/practice and/or professional conduct
3. Complaints procedure
4. Competency standards
5. Course accreditation
6. CPD
7. English language requirements
8. Mandatory declarations
9. Professional indemnity insurance
10. Practitioner certification requirements
11. Recency and resumption of practice requirements.

NASRHP’s aim in establishing this core set of standards for all member professions is to:

*“… facilitate national consistency in quality and support for self-regulating health professionals and satisfies national and jurisdictional regulatory requirements, including the National Code of Conduct of health care workers*” (from website).

Although this is not directly relevant to the current certification project, it may be interesting to note that, in its review report (AHMAC, 2018), the review team proposes amendment of the NRAS to allow unregistered health and social care professions to apply to access the skills and expertise of the Accreditation Board and operate their accreditation activities under the umbrella of the Accreditation Board, subject to specified conditions and in a manner that would have no implications for the registration of those professions. All applications for registration would continue to be dealt with through established Ministerial Council processes and in accordance with the COAG Health Council agreed criteria.

# Description of project activities

## Project governance arrangements

The two largest professional associations Australian Institute of Medical Scientists (AIMS) and the Australian Association of Clinical Biochemists (AACB) agreed to lead an inclusive process of engagement with other medical science professional groups, as well as other key stakeholders such as employers and accreditation standard setting and assessment agencies. AIMS was the official project sponsor for a successful application for funding to QUPP. The project commenced in July 2017.

A key governance arrangement has been a Project Coordination Group that includes the AIMS and AACB Presidents and CEOs and selected other participants. The Project Coordination Group comprised:

* Associate Professor Tony Badrick, Chief Executive, RCPAQAP (Chair)
* Ms Robyn Wells, President, AIMS
* Ms Helen Martin, President, AACB[[5]](#footnote-6)
* Mr Michael Nolan, Chief Executive Officer, AIMS
* Dr Kevin Carpenter, Chief Executive Officer, AACB[[6]](#footnote-7)
* A/Prof Bruce Bennetts, National Pathology Accreditation Advisory Committee (NPAAC) representative
* Ms Suzanne Petrie, Department of Health.

The HCA project team has been guided by the Project Coordination Group. The PCG met a total of 11 times either face to face or by teleconference starting with the first meeting in July 2017 and the last in April 2019.

## Initial research processes

Prior to extensive consultation with stakeholders the project undertook several actions to establish the best practice basis for development and implementation of a certification scheme. This included a literature review, case study analysis (of existing self-regulated health profession schemes in Australia) through website interrogation and interviews, review of overseas ‘certification’ type arrangements for medical scientists (including in the UK, South Africa, USA, Ireland), and interviews with other key stakeholders (e.g. NATA, NPAAC, RCPA) identified through a stakeholder analysis.

The findings of these research processes were detailed in a Discussion Paper[[7]](#footnote-8) published in 2017 and used primarily to drive consultation processes (described below) between 2017 and 2018. Some of the key findings are summarised below.

## Stakeholder engagement & consultations

### Key stakeholder workshops

After circulation of the Discussion Paper, a **full day workshop** was held in Sydney on
27 November 2017 facilitated by the HCA team and attended by participants nominated by a wide range of interested professional and employer organisations.

The program included a mix of presentation of findings from the literature review, case studies and stakeholder interviews, large and small group discussions, and the use of an online polling methodology that was used to instantaneously gauge the ‘temperature’ of Workshop participants on key issues. This methodology allowed for active engagement by all group members and for themes to be developed and adapted based on input from all participants throughout the course of the day.

A **follow-up full day workshop** was convened by the HCA team on 9 February 2018 to continue discussions from the first workshop. The primary focus of the second workshop was to conclude the discussions from the first workshop but to also provide stakeholders with a meaningful opportunity for further in-depth discussion with peers and to share and represent perspectives from across the medical science workforce sector.

Prior to this follow-up workshop, participants were asked to complete a survey to initiate the discussions at the workshop. Results from the survey were presented and discussed and a review of the findings from the previous workshop was also presented. The primary activity of the workshop was attendee participation in small and large group discussions (large group discussions were facilitated by HCA) to allow for exploration of key themes and to collectively develop participant ideas and concepts.

A total of 29 persons participated in one or both of the two Workshops, with the majority attending both. The full list of Workshop participants with their immediate stakeholder affiliation is provided below.

Table 1: Workshop participants

| Organisation | Participants |
| --- | --- |
| Chair of the Project | Tony Badrick (NSW) |
| AIMS | Robyn Wells, President |
|  | Mike Nolan, CEO |
|  | Tony Woods (SA) |
|  | Michael Lynch (NT) |
| Organisation | Participants |
| Chair of the Project | Tony Badrick (NSW) |
| AIMS | Robyn Wells, President |
|  | Mike Nolan, CEO |
|  | Tony Woods (SA) |
|  | Michael Lynch (NT) |
|  | Richard Hanlon (TAS) |
|  | Samantha Austin (WA) |
| AACB | Peter Ward, President |
|  | Kevin Carpenter, CEO |
|  | Intissar Bittar (VIC) |
|  | Andrew St John (WA) |
|  | Peter Vervaart (TAS) |
|  | Helen Martin (SA) |
| HGSA | Louise Carey (NSW) |
| ANZSBT | Greg Irwin (Regional NSW) |
|  | Simon Benson (NSW) |
| ASC | Jenny Ross (NSW) |
|  | Terese Boost (QLD) |
| THANZ | Joanne Begg (Qld)/Tina Pham (VIC) |
| ASCIA | Chris Bundell (WA) |
| FSA | Kristy Demmers (QLD) |
|  | Sally Catt (VIC) |
| Cytometry Society | Sandy Smith |
| NATA | Andy Griffin |
| RCPA | Paul Williams (NSW) |
| Public Pathology Australia | Michael Whiley (NSW) |
| Australian Pathology | Nick Musgrave (QLD) |
| NPAAC | Bruce Bennetts |
| Department of Health | Suzanne Petrie |

From the workshops a draft Position Paper was created. This went through two further iterations following more consultations before acceptance by the PCG.

### Delphi Conference

A Delphi Conference cohort of 59 participants was constructed from workshop participants and a range of other added stakeholder interests (union representatives, employer representatives, additional professional associations). The Delphi Conference method is a structured communication technique or method, originally developed as a systematic, interactive forecasting method which relies on a panel of experts (Rowe and Wright, 1999). The experts answer questionnaires in two or more rounds. After each round, a facilitator provides an anonymised summary of the experts' forecasts from the previous round as well as the reasons they provided for their judgments. Thus, experts are encouraged to revise their earlier answers considering the replies of other members of their panel. It is hoped that during this process the variation in the answers will **decrease** and the group will converge towards a consensus.

The first round of the Delphi Conference saw a draft Position Paper and a survey to guide responses to the Paper sent to all participants. Responses to at least one “position” of the Paper (there were a total of nine positions) were received from 35 conference participants. Most respondents had a scientific professional association relationship while others identified more with employer or worker representative bodies or with NPAAC. Representation of broad stakeholder interests was achieved, although rural and union stakeholder perspectives did not feature highly in the first round and were therefore a focus in the next Delphi Conference round.

In Round 2 of the Delphi Conference, a total of 70 participants were administered the revised Position Paper and the survey to capture responses. Responses to at least one ‘position’ in the paper were received from 25 participants, with many indicating they had nothing to add to their first-round comments. In all, 43 participants (61%) provided a response to at least one of the Delphi rounds.

At the conclusion of the Delphi Conference a final Position Paper draft was published[[8]](#footnote-9).

### Assessment of levels of agreement

The Funding Agreement required a level of agreement of at least 60% to be obtained between key scientific organisations on the recommended elements of the certification model.

One of the most astounding successes of the consultation process for this project was the journey towards consensus of all the 11 professional associations most closely involved in the development of the certification scheme[[9]](#footnote-10). From a starting position of disparate stakeholder interests, potentially conflicting objectives, and many years of mistrust between associations, a cohesive and largely complete consensus as to what and how a certification scheme should evolve has emerged.

The level of consensus achieved can be demonstrated quantitatively following Round 2 of the Delphi Conference (see Figure 3). The proportion of respondents completely agreeing with the final stated position ranged from a low of 60% to a high of 87%. When ‘completely’ agree and ‘mostly’ agree are combined, the consensus on individual positions then ranges from a low of 87% to 100%. This is well above the required 60% performance indicator.

Figure 3: Level of consensus achieved in the Delphi Conference by proposed positions

The small proportion of respondents not agreeing at all with positions was quite low - between 5 and 10%. The source of disagreement was mostly an interest outside of the 11 professional associations.

### Final workshop

A **final full day workshop** was undertaken in November 2018 with the participants of the first two workshops. This workshop focused on the small number of remaining elements where some elements of discord remained (see above). The workshop group agreed on a final position for all the elements of the certification scheme.

# Typical elements of professional certification models

## Founding principals

Prior to designing and establishing a certification system, the founding principles or values of the system should be clarified and agreed upon.

The School Principal Certification system, established in Australia in 2015, was founded on the following principles (Ingvarson, 2017) – that is that:

* the system was owned by the profession
* certification was based on valid and reliable evidence of successful leadership initiatives—not an academic qualification or a curriculum vitae
* certification was portable and not tied to a position specific to a particular school or school system
* certification was distinct from performance management processes.

Clarity and consensus on the mission and intent of a certification system is critical and, along with founding principles, will influence the core elements and design of a system. Depending on the context the intent or purpose of certification, systems may contribute to one or all the following:

* elevate the credibility and professionalism of individuals and the quality of the services they provide (Knapp, 2000)
* enable individuals to demonstrate their commitment to continuous improvement (Chung et al., 2011)
* provide an objective and independent process to demonstrate specialised knowledge and skills (Gourley et al., 1997)
* enhance quality and protect the public (Ayres et al., 2009).

## Core certification elements

Several core elements need to be considered in the design of a quality certification system and attempts have been made to describe common components of systems (Chanduvi et al., 2011; Knapp, 2000). The final design of the system will of course be highly contextual, yet there are critical features or elements that need to be considered for any system.

Quality certification systems are dependent on clear founding principles and consensus on the mission and intent of a certification system. There are also core elements that need to be considered in the constructing of a scheme. From a review of the literature and a study of seven certification schemes (four Australian health professions and three overseas medical scientist schemes) the following elements are common considerations for most schemes:

1. **Participation requirements** – is the scheme participation voluntary on the part of workers or made mandatory by government intervention (e.g. legislation) or employer requirements?
2. **Levels of certification** – how should a certification system be developed to cater for occupational hierarchies and functions (vertical levels) as well as levels proficiency or competence (horizontal levels)?
3. **Entry requirements** – does the scheme require completion of some ‘qualifying’ process, normally an ‘accredited’ course of training or a sufficient level of workplace experience, or is entry open and conditional only on the assessment requirements of the scheme?
4. **Methods of competency assessment** – what types of assessment processes are employed and what balance has been struck between validity, objectivity and implementation burden (cost). Methods can include one or more of supervisor reports, preparation of a competency-based portfolio and/or completed checklist of professional development activities, reflective skill assessment/ self-assessment, observation, examination, competency-based workplace assessment, interview?
5. **Competency-based certification** – is the scheme based on academic qualifications or on a more detailed description of competency requirements, or both? And if based on specially developed competencies, what is the source of authority for their development and maintenance?
6. **Recertification and maintenance of certification** – to ensure support from and accessibility for individuals how should recertification be assessed, how often should it occur and what are the cost implications?
7. **Accountability and governance** – what are the structures and processes, such as by-laws, board membership and administrative systems, that need to be implemented to ensure independence and sustainability?
8. **Sanctions** – what are the penalties and processes for non-compliance of the certification system as well as appeals processes and conditions?
9. **Cost of certification** – what is the cost of implementing the scheme and is the burden of funding support wholly borne by scheme participants or shared with other stakeholders (e.g. employers, regulators, government)?

The certification scheme to be established in the next 12 months has been defined on each one of the above elements. In the following pages the details for each of these elements is provided.

# Certification Scheme details

The following section outlines each of the final positions on key Scheme elements achieved through the structured consultations. Some of the positions still require development of details by the new governance arrangement, so an indication of the known and emerging actions that may be required prior to the proposed official launch of the scheme on 1 July 2020 are provided.

## 1. Accountability and governance

It is proposed that a new independent governing body be set up as a limited (by guarantee) liability company. The proposed name of the company is *the Australian Council for Certification of Medical Laboratory Scientific Workforce (ACCMLSW) Limited*. The initial ‘owners’ of the company are called ‘members’ and are those relevant professional associations that have consistently indicated support for the Scheme’s development, are committed to supporting its establishment with financial or in-kind contributions and are willing to contribute a member fee.

The proposed structure of the governing board of the company will made up of up to nine directors, as follows:

* five core Directors made up of a representatives from Member associations
* one Consumer Representative
* two to three additional Board members as nominated and invited by the core Board members.

Although it would be ideal to incorporate legal and financial expertise within the overarching board, these skills can otherwise be accessed via the establishment of a Standing Advisory Committee that includes this expertise. Likewise, a well-constituted and supported Standing Advisory Committee can also achieve access to critical advice from consumer representatives, employer groups, unions, quality standard setters (such as NPAAC and RTAC) and any other identified key stakeholders.

Members will elect the core Directors of the Board based on some level of proportional voting capacity (see overview of proposed governance structure on the next page). All Directors would be required to act independently of their nominating body in pursuing good governance of the scheme and to be appropriately trained to undertake their role as a Board Director according to the relevant legislative requirements of that role. It is proposed that all Directors (except perhaps the Consumer Representative) be able to demonstrate the achievement of a suitable recognised training course for company directors (or have warranted their willingness and capacity to fulfil that requirement within a specified time period).

The term of directorship is to be either two or three years and the turnover should be staggered to ensure retention of corporate memory. The new body would need to act as an independent body that is able to make decisions on the conflicting advice that may be received from its shareholders (namely, participating professional organisations whose members are likely to seek certification). After the initial start-up phase, the day-to-day management of the Scheme would be undertaken by paid staff operating under the broad guidance of the Board (as per the model in place for other health profession certification bodies), noting that it is likely there will be limited funding for staffing, at least in the initial phases of the scheme’s establishment and operation.



The Standing Advisory Committee will be made up of representatives from all participating associations (shareholders), employers, unions, consumers, and quality standard setters, as well as people with relevant legal and financial skills and experience as needed to supplement the board’s collective expertise in those areas. In line with arrangements utilised by other health profession certification bodies, members of the Standing Advisory Committee would assist the governing board with a range of activities, including formal sub-committees that would be established as required to undertake both core and one-off activities.

In addition, advisory structures would be created and/or endorsed to reflect core discipline interests and to provide a source of content-specific advice to the board in relation to discipline-specific scopes of practice and associated assessment mechanisms. These advisory structures would in some cases require the cooperation of multiple associations focussed on the same or similar discipline.

Over time, it is anticipated that suitable certification may be made available to applicants from a range of disciplines (horizontal applicability of the scheme) and to practitioners from a range of competency and skill levels - for example, to phlebotomists, senior scientist[[10]](#footnote-11) and clinical scientist (as per NPAAC definition for supervision of clinical aspects of the testing process) – i.e. vertical applicability of the scheme. The top level of certification would need to be able to exceed but must at a minimum fulfil the NPAAC requirements for supervision (clinical governance) of Category B laboratories.

The construction of the final governance arrangements will need to focus first and foremost on fair and independent governing practice for the new scheme to ensure that it is not unduly influenced by the interests of other organisational entities. However, it is likely that guidance to this body from stakeholder organisations will continue for some time to be drawn from organisations with existing access to larger numbers of actual or potential scheme participants. Therefore, it seems sensible that some allowance for stronger representation of that participant voice should be made, with flexibility built into the governance arrangements to acknowledge and reflect shifts in this influence base over time (e.g. to reflect an increasing workforce in an emerging technology and associated representation in the scheme). This has been reflected in the proposed governance arrangements in the form of three levels of Member participation in AGM voting rights and a confirmed Board representative for each organisation that has 1,000 or more potentially eligible scheme participants. It may also be worth considering that some allowance is made in the governance arrangements and operating costs of the scheme for the use of a facilitator for major discussions requiring agreement by the shareholders to reduce the risk of discussions getting “stuck” prematurely.

### Action required:

* An Interim Board structure made up of representatives of the medical laboratory science professional associations who will become formal Members of the scheme will be needed to steer the implementation process
* Professional legal and accounting advice will be required to inform the establishment of an initial trust fund and subsequently the creation of the company structure and legal governance requirements. A draft Constitution has been prepared by HCA to support this finalisation process (See the Implementation Plan). A phased process of full implementation of the scheme that maximises participation in the scheme and allowing adjustments to be made along the way should be agreed by Members and informed by the views of other interested stakeholders such as employers where relevant.

## 2. Participation requirement

Despite strong support for compulsory certification, stakeholders conceded that, in practice, individual participation will need to at least commence on a voluntary basis. The recent final report of the Accreditation Systems Review (COAG, 2018), which considered a range of issues in relation to assuring the quality of health professional service in Australia, confirmed the likelihood that there would be little expansion of additional health professions under the Australian Health Professions Regulatory Authority (AHPRA) registration scheme. Almost all (96%) of the Delphi conference participants indicated that they accepted this premise either completely or almost completely.

In terms of government policy, therefore, a medical scientist workforce certification scheme would need to be implemented (at least initially) based on voluntary participation. This means that one of the key challenges that the proposed certification scheme faces is for it to attract as many participants as possible to make it viable. The key attractions for participation in the proposed scheme have been identified as:

### For workers

* recognition of each workforce member’s professional standing as part of Australia’s health service workforce
* potentially competitive advantage in seeking promotional opportunities and in seeking to progress along a career path
* potential for greater workforce mobility as employers are better able to recognise overseas training (since individual’s competence would be certified) and experience between jurisdictions in Australia is more readily accepted

### For professional associations

* raising awareness of the role that this workforce plays in conducting the safe and reliable tests and procedures that support effective health care in Australia
* increasing the professional status of the medical science workforce, which might be particularly attractive to non-professional workforce categories
* increased membership especially if membership and certification can be linked

### For regulatory authorities

* identifying the risks in the testing and procedural processes that each workforce group can assist in managing, in partnership with employers, through maintenance of relevant professional practice competence
* link workforce competence to NPAAC supervisor requirements / standards
* certification can eventually be incorporated into the NPAAC-led accreditation framework that underpins regulated access to pathology funding and then into the associated laboratory assessment regime, which is managed jointly by NATA (as the approved auditing body) and the RCPA.

### For employers

* more clarity about what types of competence are required for safe practice at each level of workforce participation
* Assessment of employee competency has for many years been a requirement under the national accreditation standards framework and as part of the Reproductive Technology Accreditation Committee’s Code of Practice (RTAC)[[11]](#footnote-12) scheme requirements for scientific staff working in laboratories that undertake assisted reproductive scientific procedures. This means that an effective certification scheme for laboratory staff across a number of levels could provide to employers/the owners of laboratories evidence of worker competence.
* Leverage some or all the following investment that is already made by best practice laboratory owners and their employees to promote and assess competency:
	+ quality systems
	+ training records/competency assessments
	+ availability and accessibility of continuing education and professional development
	+ attendance at conferences/ meetings/ educational sessions
	+ time required for completing portfolios/logbooks
	+ IT support for logbooks/portfolios
	+ involvement in stakeholder groups (membership fees/attendance at meetings/ teleconferences)
	+ release of staff for roles as NATA or RTAC technical assessors
	+ IT support for online learning and supervisor input into assessment requirements.
* There is a reportedly high degree of variation between pathology laboratories in terms of the process of assessment and documentation of individual worker competence and this would become evident with a certification scheme (to the possible advantage of best practice laboratories).

#### For consumers

* Raised awareness of the professional scientific workforce that contributes to pathology service provision
* Reassurance that appropriate professional standards have been set, are reinforced by continuous professional development, and are monitored to ensure that at least minimum standards are met.

Many respondents felt that partnership with employers will be critical because the laboratory context in which scientific staff members undertake their professional practice is significant and influential and that work is undertaken most often in a team-based setting. Although participation in the scheme will be voluntary initially, it may become increasingly valued by employers over time. In that case, in years to come, there may be informal or even formal encouragement from employers for individuals to participate in the scheme and those who have not joined the scheme may therefore come under some pressure to do so. It may also become an influencing factor in recruitment of staff i.e. perceived as a competitive advantage.

Avenues for achieving structural support in favour of participation will continue to be explored. This will primarily take the form of aligning the scheme to employers’ requirements in relation to the current NPAAC and RTAC accreditation standards relating to staff competency and other key quality and safety issues relevant to the contributions of the scientific profession, particularly relevant clauses of AS ISO 15189 and other relevant NPAAC Requirements noted earlier on page 8 of this paper.

Cost issues will be important in achieving a high level of voluntary participation in the scheme (see later section), but significant effort will also need to be invested in raising awareness of the scheme, highlighting the shared benefits with employers, and promoting worker participation. The benefits of the scheme as outlined above will need to be “sold” to all interested stakeholders, but the scheme will be primarily focussed on assuring the individual practitioner’s professional standing and their own responsibility for maintaining professional competence and ethical standards.

### Action required:

* Continued engagement with all key stakeholder groups, including employers
* Collation and dissemination of the key benefits of the scheme
* Co-operation with relevant standards-setting and assessment bodies to take advantage of opportunities for alignment of the scheme with quality and safety initiatives
* Build collegiate relationships with similar certifying bodies to explore options for mutual support and collaboration, including in relation to accreditation and self-regulation of Australian health profession standards.

## 3. Levels of certification

Broad opinion, even from supporters of a number of vertical and horizontal levels of certification, seems to be that the original proposed certification model is too complex, and that complexity could present unreasonable risk to initial scheme implementation.

Stakeholders are in relative agreement that a certification scheme should include several vertical levels of the medical ***scientist***workforce. While there is broad support also for inclusion of other levels of the medical science workforce in a certification scheme, there remains debate about the timing of the introduction of these workforce categories (at the commencement of the scheme or at a later stage). The exception appears to be for a technician level of certification.

There remains, though, a recognition that:

1. lower levels of the medical science career path had potentially the most motivation for certification, and
2. the less highly qualified and skilled laboratory workforce component is that segment most associated with medical laboratory risks that were most amenable to amelioration through maintenance of competence standards (e.g. safe transaction of patient and sample/specimen identification).

The **vertical levels** of certification proposed for the scheme (both initially and at later stages) are as laid out in Table 2 below. The proposed certification levels in this table are linked to levels of the Australian Qualification Framework (AQF)[[12]](#footnote-13) which provides a stable structure to underpin the descriptions of role, skill, knowledge and responsibility for the scheme, one which places the medical science workforce on an equal platform with other workforces.

Table 2: Summary table of proposed levels of certification

| Proposed certification level | Career pathway / Description | AQF Level\* | Stage of introduction of level |
| --- | --- | --- | --- |
| A | Laboratory technician  | Level 5 / 6 | Scheme commencement |
| B1 | Conditionally certified medical scientists with less than two years practical experience | Level 7 | Scheme commencement |
| B2 | Medical scientists capable of proficiently performing laboratory science processes independently (could be generalist or have attained greater depth of competence in one or more specialist discipline areas) | Level 7 | Scheme commencement |
| C | Senior scientist / Senior discipline specialist  | Level 8 | Stage 1 |
| D | Clinical scientist  | Level 9 | Stage 2 |

Brief notes on each of the proposed certification levels are provided below:

1. **Technical officers -** Some stakeholders argue that this level of certification is important to provide technical officers with professional motivation, in particular in those areas of practice where qualifications are less common or less directly relevant to employment. The Scope of Practice / competency framework document covers the work of technical officers adequately.

There is agreement that tertiary-trained scientists being employed in technical officer roles should not be excluded from seeking certification as a medical scientist if they can demonstrate they can meet the competency required[[13]](#footnote-14).

Stakeholders have not supported the proposed concept of a ‘Technician” certification level being divided into officer and senior officer levels but noted that, as the scheme evolves, it might attempt to recognise the competence of more senior roles in this level.

### Levels of certification

1. **Medical scientist (B1/B2) -** would be the basic level of certification available to those who can demonstrate that they are competent to practise as an independent professional medical scientist. For inexperienced scientists (new graduates, possibly newly migrated scientists) certification would be based on qualifications and provided on a conditional basis till practical experience could be accumulated and competence demonstrated (see later section on ‘Entry Requirements’). This conditional level of “provisional” or “entry-level” scientist certification would operate much like how overseas trained doctors in Area of Need positions around Australia obtain conditional registration.

Medical scientists work in many different workplace contexts where the job requirements can be quite specific. A degree of ‘specialisation’, though, does not necessarily imply greater competence – rather, it could just reflect a narrow skill set at the same level of competence. Further consideration is needed in relation to how competence across various scopes of practice and types of laboratory should be determined to meet employer requirements from the profession and assure public safety. The competency framework specifies generic competencies – i.e. those that are essential to underpin all forms of medical science work – but they will most likely need to be assessed in the context in which they are to be applied. In other words, the certification assessment process should be adaptable enough to be able to consider the core skills required by an individual’s current workplace or workplace type (e.g. multidisciplinary or single discipline).

1. **Senior Scientist/Senior Discipline Specialist –** in addition to reflecting a greater level of experience and professional competence in core scientific skills, this level of certification is likely to be applicable to greater levels of specialisation in “horizontal”/discipline-specific competency development where workers can demonstrate autonomy, well-developed judgement, adaptability and responsibility and *be able to transmit knowledge, skills and ideas to others*. All the specialist areas could potentially be identified as specific certified specialist areas, but the determining factor would be the level of interest of the discipline-specific professional association and their willingness and capacity to fully support the content infrastructure needs of the scheme (competencies, assessment guidelines and tools, assessment support, etc.).

To support the assessment of competence, further work will be required on the competency framework to cover ‘specialist’ competencies and completion of this work (by the relevant professional association or a governance working party arrangement) will be a prerequisite for the inclusion of that discipline’s recognition as a specialist area in the certification scheme. Many of the specialist professional associations and societies will already have established practice in place or developed some thinking around specialised skills and knowledge, and these could form a part of the basis of further development in this area of the scheme’s potential operations. For example, the cytotechnologist testing and recognition process (which includes workplace supervision and a final examination) is fully operational and could potentially be adopted in its current form. Likewise, full AACB membership is only offered after completion of a minimum period of workplace experience in clinical biochemistry and passing an examination which is recognised as similar in standing to a Master’s degree.

### Levels of certification

Other disciplines have expressed interest in developing frameworks to support similar assessment regimes for competence in their fields. The need for ensuring some parity of skill and competence assurance provided by these discipline-specific assessment methods has been widely acknowledged during consultations.

An alternate approach would be to use the same competencies but, to obtain specialist certification, the scheme participant must demonstrate the required competencies ***in the context*** of the specialist workplace and work functions. This is a common way of acknowledging some level of specialisation within the vocational education and training (VET) sector.

The inclusion of managerial classes within the ‘specialist’ certification category was not supported by a majority of stakeholders. While most accepted that management competencies should be developed and assessed, they argued that it was outside of the science domain, and therefore not suitable for certification (defining, developing, assessing) within a scientific workforce scheme.

1. **Clinical scientist** – The ‘clinical scientist’ definition from NPAAC refers to someone who has at least 5 years’ relevant medical laboratory experience and who is responsible for supervising a laboratory and possesses one or more of the following qualifications by examination:

(a) a Fellowship of the Australasian Association of Clinical Biochemists

(b) a Fellowship of the Australian Institute of Medical Scientists

(c) a Fellowship of the Australian Society for Microbiology (medical microbiology or clinical microbiology)

(d) a Fellowship of the Human Genetics Society of Australasia (biochemical genetics, cytogenetics or molecular genetics)

(e) a Fellowship of the Faculty of Science of the Royal College of Pathologists of Australasia

(f) a Fellowship of the Australian Society of Cytology

*or*

a Doctorate of Philosophy, [Australian Qualifications Framework](https://www.aqf.edu.au/aqf-second-edition-january-2013) level 10[[14]](#footnote-15) or equivalent doctoral level degree, in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising.

In Table 2 above, the possible vertical levels of Laboratory Assistant and Phlebotomist/Specimen Collector are not included in the list now but may be included later. Several stakeholders thought that the certification process was, if anything, more appropriate to these categories of the scientific workforce, which (a) represent the face of medical science laboratories and (b) are known to be the source of the most common laboratory errors, than to other forms of scientific workforce. Their thinking was that both consumers and the workers themselves would benefit most from certification at these levels.

### Levels of certification

While the rest of the stakeholders (the majority) were not unsympathetic to these arguments, the over-riding consideration in the views expressed focussed on reducing complexity in the scheme start up. It is possible that the introduction of these workforce categories would become easier at a later stage once the scheme had demonstrated viability. However, no timeframe has been placed on this possibility.

Although the initial certification levels have been limited to the inclusion of just two groups - Scientists and Technical Officers - it is anticipated that the scheme could expand relatively quickly to incorporate a range of other workforce groups/levels over time. In order to support that process, it would be beneficial for scheme stakeholders to continue to collaborate to further define common and/or optimal career pathways in the medical laboratory workforce and delineation of boundaries/transitions between workforce groups. Stakeholders recognise that there can be significant variation of role delineation both within and between workforce groupings and that clarification of these issues will take some time to ensure that all contexts have been addressed.

### Action required:

* Certifying body governance mechanisms to engage closely with all interested professional organisations (both scientist and technical officer-focussed) as the core elements of the scheme are finalised and refined in the initial phases of implementation.
* Discipline-specific professional groups to continue to monitor the capacity of the core framework to address high priority professional competencies.

## 4. Entry requirements

### Entry requirement overview

Different certification scheme entry requirements are proposed for different certification levels:

* For a scientist, a relevant degree in Science or Applied Science (AQF Level 7 or above) would need to be achieved (and documentary evidence provided, e.g. an academic transcript of subjects successfully completed), in line with the definition of Scientist that is well established in the NPAAC accreditation framework and Medicare legislative framework. An appropriate level qualification (or above) would be one that the certifying body deems to be sufficiently relevant to support commencement of supervised practice in a laboratory. A list of acceptable courses would be created through a working group of the Certification Scheme governance arrangement and attempt to provide some level of filter but not exclude course options that already appear to be accepted by employers.
* For a technical officer, documentary evidence of completing a relevant VET sector course (or equal or higher relevant qualification, such as a science degree that would meet the requirements for entry as a scientist, or suitable evidence of achievement of competence as deemed acceptable by the their employer and documented to meet the scheme’s requirements as published in the scheme’s rules from time to time) would need to be provided (i.e. AQF Levels 5 or above). A list of relevant qualifications would be created by a working group of the governance arrangement.

These qualifications would allow access to “conditional” certified status, which would allow them to practice as part of the relevant sector of the laboratory workforce.

In addition to evidence of a relevant qualification as outlined above, for full certification applicants would need to have the equivalent of 2 years’ recent full-time experience in an Australian (or equivalent) laboratory that supports medical service provision and to have met the competency assessment requirements established for the certification scheme.

The two-year period may be shortened to account for documented competency-based training (relevant to the level of certification applied for) that has occurred during training or while undertaking other workplace roles, such as a technical officer position, or some recognition for part of that period. The extent of time reduction might vary according to the evidence of previous workplace practice able to be demonstrated, with stakeholders expressing views on appropriate exemptions ranging between nil (for entry level scientists), 12 weeks, one year and the whole two years (for experienced technical officers transitioning to scientist roles). The position provided here is that at least 12 months supervised practice is required before a candidate can attempt to be fully certified.

In addition to evidence of an appropriate level of training, other evidence to support entry to full certification might include commitment to a Code of Conduct.

The proposed initial “grandfathering” entry process for existing Scientists and Technical Officers outlined in the Participation Position will provide to the scheme a comprehensive indication of the qualifications that are currently accepted by employers and this information will be analysed over time to establish common core study components for associated roles. This information will be used to guide assessment of entry for later scheme entrants, with the core principle being that formal qualifications need to include sufficient core knowledge content that is aligned with competent professional practice in that individual’s current role. Over time, competency assessment results will allow review of potential difficulties with specific courses if patterns begin to emerge.

### Certification Requirements – Proposed Phases

To make full sense of the proposed phases of entry requirement detailed below, the reader might want to refer to Section G which outlines the implementation process in greater detail and puts these phases into context.

**Phase 2 and 3: Trial phase and initial full implementation – October 2019 to June 2023**

1. For a Medical Laboratory Scientist, evidence of a relevant qualification in Science or Applied Science (AQF Level 7 or above) and for a Medical Laboratory Technician, evidence of completing a relevant VET sector qualification or equivalent\*[[15]](#footnote-16) (or equal or higher relevant qualification, such as a science degree that would meet the requirements for entry as a scientist - i.e. AQF Levels 5 or above)
2. Evidence of minimum 2 years’ relevant recent experience
3. Willingness to agree to Code of Conduct/Ethics
4. Trial simple assessment of competencies in partnership with employers – survey data collected to assess opportunities for process improvement
5. CPD Certificate from an accredited CPD provider or an outline of CPD activities undertaken in the previous 2 years; survey commentary sought from all applicants on enablers, barriers and perceived needs for CPD and competency development/maintenance.

Data collected for evaluation of the Scheme’s operation and framework.

**Subsequent Implementation Phase: Introduction of more rigorous assessment requirements – July 2023 to 30 June 2026 (and beyond)**

1. For new applicants, Medical Laboratory Scientists will require evidence of a relevant qualification in Science or Applied Science (AQF Level 7 or above) and Medical Laboratory Technician, will evidence of completing a relevant VET sector qualification or equivalent\* (or equal or higher relevant qualification, such as a science degree that would meet the (may already be on expanding list of approved degrees)
2. Evidence of minimum 2 years’ relevant recent experience
3. Willingness to agree to Code of Conduct/Ethics
4. Assessment of core competencies in partnership with employers – assessments reviewed by the Certification Panel - 5% auditing certification and re-certification applications
5. CPD Certificate from an accredited CPD provider covering the previous 3 years; further survey data collected from all applicants on enablers, barriers and perceived unmet needs in relation to competency development.
6. Complaints, investigation and appeal process is in place – only warnings issued where necessary.

**Final Implementation Phase: Full Scheme entry requirements implementation phase – From July 2026 onwards**

1. For new applicants, Medical Laboratory Scientists will require evidence of a relevant qualification in Science or Applied Science (AQF Level 7 or above) and Medical Laboratory Technician, will evidence of completing a relevant VET sector qualification or equivalent\* (or equal or higher relevant qualification, such as a science degree that would meet the (may already be on expanding list of approved degrees)
2. Evidence of minimum 2 years’ relevant recent experience
3. Willingness to agree to Code of Conduct/Ethics
4. Assessment of core competencies in partnership with employers – assessments reviewed by the Certification Panel of10% of certification and re-certification applications
5. CPD Certificate from an accredited CPD provider covering the previous 3 years
6. Complaints, investigations and appeal process operational and sanctions applied where necessary.

#### Action required:

* Working group be delegated to finalise a Code of Conduct – relevant examples such as the following:

### IBMS – https://www.ibms.org/my-ibms/code-of-conduct

AIMS – <https://www.aims.org.au/membershipinformation/code-of-conduct/code-of-conduct>

NZ - [file:///Users/administrator/Downloads/Code%20of%20Ethics%202012.pdf](file:///%5C%5CUsers%5Cadministrator%5CDownloads%5CCode%20of%20Ethics%202012.pdf)

* Database to be established for collation and analysis of qualifications submitted for conditional and full certification
* Working group to be established to review Technical Officer qualifications and relevant experience submitted by first round of certification applicants, including requests for early admission to full registration as a scientist.

## 5. Competency-based certification

### The competency framework

The existing framework has proven repeatedly to be appropriate for the task of supporting a range of workforce related functions. Originally created to support the design and possible accreditation of courses to develop different medical scientific workforces, it provides a capacity to also support a certification scheme and a broad range of other human resource development and management functions.

For the purpose of underpinning a certification scheme, it is accepted that some further refinement of the CBS framework may be required over time, including:

* addition of some competencies to reflect continually evolving medical laboratory practice
* modification of existing competencies (especially terminology) to ensure appropriate inclusion of all scientific disciplines to appropriately be included in the certification scheme.

### Ownership of the competency framework

There was some debate within the Delphi Conference population as to who should be the ultimate ‘owner’ of the CBS framework. Some (17%) felt the PAC should remain the main custodian and continue to be responsible for its maintenance but most others felt this was not a sustainable responsibility for PAC under its current rather informal structure. Some others (another 17%) did not support the role being given to PAC but still felt the final development and sustaining of the CBS framework should be undertaken independent of any scheme governing structure. Most Delphi Conference respondents though (56%) thought that the certification scheme’s governing structure should be the ultimate custodian of the framework but in the meantime, PAC should continue to be the venue for discussions about it as well as any decisions about modifications of the framework.

How the certification scheme governing body would manage this task would be up to them, and might involve delegating to a third party, delegating to the professional associations or making modifications with help from outside experts. Most stakeholders have indicated in a range of ways that they would be disappointed if the professional associations were not involved in the ongoing shaping of the CBS framework, at least in framing competencies specific to their respective disciplines, and the proposed accountability and governance structures (see later section) for the scheme has taken those views into consideration.

### High risk competency focus

A slight majority of stakeholders believe that the focus of competence assessment should be upon the competencies that address the known **high-risk** areas of laboratory practice as an initial focus of the proposed certification scheme. This focus on potentially high-risk areas of professional practice combines the professional interests of the scientific workforce, the responsibilities of laboratory owners and the safety and quality interests of consumers. In theory this approach also involves less work, since the focus of developing assessment tools can be on selected competencies rather than all that might be appropriate to performance of a particular work role.

A focus on high risk competences, at least initially, is likely to make the biggest difference for assuring the public (and employers) that a certification scheme can be a useful contribution to achieving safe and effective testing. The high-risk competencies could be identified by an expert group possibly informed by analysis of incident monitoring data from the longstanding Key Incident Monitoring & Management System (KIMMS) external quality assurance program to provide an evidence base. The use of KIMMS data in competency assessment was favoured by most Delphi Conference participants.

In the light of the Certification Project’s discussions and in collaboration with the PAC (plus invited others, such as FSA, THANZ, and ACS), the current CBS framework has been endorsed as largely fit for purpose for the time being. The framework will be subject to review by the certifying body and its participating stakeholders as the competency assessment process associated with the scheme develops.

## 6. Methods of competency assessment

Given the range of views expressed and some strong opposition to elements that were well accepted by others, the following suite of somewhat revised options was developed for consideration over time:

1. **Online learning and testing modules (focussed on all elements of the competency framework) - The** Certifying body (and/or approved third party provider/s) will need to offer module-based online learning and testing options which certification applicants will need to successfully navigate. Applicants will complete at least an agreed number of modules over the course of the conditional period of practice across an agreed number of competencies from the framework (focus may or may not be required on generally agreed “high risk” competencies). Progress from one module to the next will require successful completion of an online test that draws randomly on a bank of questions. The certifying body will be responsible for developing and/or approving the bank of suitable modules and test questions, potentially informed by analysis of relevant KIMMS data[[16]](#footnote-17)
2. **Portfolio of evidence of professional development, which would include –**
3. A relatively simple **logbook** which aims to raise awareness of the CBS framework at an early career point but is designed to support straightforward checklists (that are simple for staff and employers to use for agreeing on successful completion of activities) and logging of other competency-related activity not covered by the checklists[[17]](#footnote-18). Completion of the logbook would require a certification applicant to cover a full range of competence areas, not just those associated with a current job or role.
4. **Evidence of other professional development activities** undertaken during the conditional practice period[[18]](#footnote-19).

Further work is required to support the implementation of effective competency assessment processes that are comparable between individuals and workplaces and that guidance in this area would be welcomed by professionals, employers and accreditation assessors. This work would benefit from the continuing involvement of stakeholder representatives and their nominating bodies to ensure that the sector benefits broadly from the development and/or promotion of efficient but effective competency assessment methods, which could in turn be adopted and/or recognised by the certification scheme. A range of options should be canvassed, including various online options and face-to-face methods, ensuring that professionals working in rural areas are not disadvantaged. Where existing competency assessment arrangements can be incorporated and recognised, those options should be explored as well.

In addition, the potential to align the certification arrangements with competency assessment of individual workers as part of the laboratory accreditation assessment arrangements should continue to be explored, for the benefit of both workers and employers, potentially for the efficiency of the certification scheme, and to promote the anticipated benefit of the proposed certification scheme in supporting the competence of the medical science workforce.

This work should be prioritised in the initial three-year period of the certification scheme and prior to the first round of recertification when the first substantive application of competency assessment requirements will be initiated. It is anticipated that the focus on competency assessment will increase in emphasis over the course of the scheme’s progression.

### Action required:

* Working group to be established to guide the proposed competency assessment development project (including employer representatives)
* Database to be established for collation and analysis of CPD information – working group to be established and expertise of existing CPD administrators to be leveraged
* Ongoing review and environment scanning of existing CPD options that can be undertaken by scheme participants and applicants and findings analysed for gaps and unmet needs.
* Working group to be established to consider and reflect upon the competency-related data that is submitted by the “Beta tester” and Early adopter” scheme entrants and to feed that analysis into further refinement as required for the maturing scheme.

## 7. Recertification

The proposed position is a certification frequency cycle of 3 years. In line with recertification systems employed by various certification schemes nationally and internationally, it is proposed that a points-based system is adopted for the proposed scheme. That is, scheme participants will need to undertake relevant activities to accumulate enough points within every re-certification period.

The following rules would apply to the certification/recertification process:

* Certification would be time limited for three years and recertification would automatically be required when the certification period expires.
* If an individual seeks certification within two years after certification has expired, they may seek re-certification either through a full certification process or by writing to the board and providing evidence for enough CPD points having been accumulated for the previous three years as required for re-certification.
* If an individual’s certification has lapsed and not been renewed within five years or more of the initial certification (or last date of re-certification), they will be required to undertake full certification and pay the full fee for certification.

### How does the points-based system work?

Based on the points-based system of the comparable programs described, it is proposed that individuals seeking recertification (or maintaining their certification) should accrue a minimum amount of points over the three-year period. Once the scheme is established, it will be necessary for the governing board to determine the total points to be accrued and the value or points to be assigned for each type of CPD evidence, but a suggested approach is provided below.

A range of evidence types are proposed according to the following four categories of evidence:

1. Workplace
2. Professional service
3. Post graduate studies and professional development
4. Publications and presentations.

The types of evidence for each category are listed in Table 3 below. While there was some diversity of views expressed in the Delphi Conference about how evidence requirements should be weighted, they have been used to guide values in the Table. Each type of evidence has been assigned a value from between five to 30; individuals would need to accrue a total of 100 points over a three-year period (the final values would need to be determined by the governing board).

Table 3: Types and categories of evidence for recertification

| Category | Activity | Points |
| --- | --- | --- |
| Workplace | Supervisor assessment | 10 |
| Undertake QA research project | 20 |
| Formal mentoring within the workplace (employer-recognised) | 10 |
| RCPA QAP results (or results from other recognised external QA schemes e.g. “we have EQASRM and FertAid in the fertility industry”) | 10 |
| Professional service | Membership of committees/professional societies/stakeholder groups | 20 |
| Attendance at conferences/meetings/educational sessions/journal clubs etc. | 5 |
| Registration/participation as a NATA peer technical assessor | 15 |
| Professional development training activities | Participation in training webinars/lunchtime or post work workshops / courses (2 hours or less) | 5 |
| Attendance at structured CPD workshops/courses (at least 1 day) | 10 |
| Post graduate studies | Postgraduate certificate (relevant to the profession) | 30 |
| Completion of discipline specific course conducted by relevant professional body or institute | 30 |
| Postgraduate diploma (relevant to the profession) | 50 |
| Fellowship or PhD (NPAAC definition) | 30 |
| Publications and presentations | Editing a book | 10 |
| Authoring a chapter in a book | 15 |
| Author a book | 25 |
| Authoring a journal article (peer-reviewed) | 20 |
| Authoring a journal article | 15 |
| Presentations at meetings/workplace/professional societies  | 5 |
| Conference presentations | 10 |

### Underpinning rules for evidence requirements

The system of recertification should be underpinned by similar rules as utilised by the Australian VET sector for determining appropriate evidence – that is, that evidence should be valid, sufficient, current and authentic.[[19]](#footnote-20) The parameters for these rules would need to be defined, for example:

* valid – what type of evidence would be acceptable to assess ongoing quality and competence?
* sufficient – how much evidence would an individual need to provide? How will quality be defined? What type of evidence would be deemed relevant?
* current – for what period would an individual’s evidence be valid?
* authentic – what will constitute authentic evidence and how will this be assessed (e.g. through a random auditing process)?

The processes for recertification and maintenance of certification will need to develop over time. Despite some associations currently offering or endorsing participation in CPD schemes, information collected during the Certification Project to date has revealed that the current rate of externally documented CPD is very low by workforce percentage and existing schemes do not generally offer content that clearly links to competency development and/or maintenance. It is likely there is other information currently held by professionals and employers that could be drawn upon and that the two initial workforce groups (and particularly the Technical Officers) and their employers could benefit from the development and availability of a range of additional, cost-effective CPD options.

Although membership of a professional association will not be a requirement of participation in the proposed certification scheme, such membership is likely to assist individuals in meeting and documenting their CPD participation. This will particularly be the case if existing CPD administration schemes progress to more competency-focussed content over time, as has been the experience of other certification scheme providers in overseas jurisdictions and/or other health professions.

### Part time and leave arrangements

The following draft policy positions have been prepared during the course of the certification project and will require further reflection and consideration by a delegated working group or committee of the Interim Board.

**Part time and casual workers**

Individuals working part time or casual are required to accrue 100 Continuing Professional Development (CPD) points over three years to maintain certification through the Scheme. As a certified Scientist or Technical Officer, completion of CPD is a requirement of certification, regardless of the number of hours worked each week.

Full-time equivalent is 38 hours per week. The maximum number of hours that can be counted per week is 38 hours. Part-time is 18 hours or less per week. This can be completed on a part-time basis as agreed with the Board.

**Leave arrangements**

Individuals on approved leave from the Scheme (such as due to parental leave, sick leave or study leave) will still be required to accrue 100 CPD points (or 20 hours average per year of CPD learning), regardless of circumstances, if they want to maintain certification. This can be completed over an extended period, as agreed with the Board.

**Recency of practice**

Applying for recertification

Recency of practice means that a Medical Laboratory Scientist or Technician has maintained an adequate connection with, and recent practice in, the profession since obtaining certification.

To be eligible for recertification, you must have carried out a minimum of:

* 450 hours of practice during the three-year period immediately prior to the start of the recertification period, or
* 150 hours in the previous year.

Returning to practice[[20]](#footnote-21)

If you have two or more years working experience as a certified Medical Laboratory Scientist or Technician and are returning to practice, you are required to meet the following requirements for recertification:

* if you have had non-practising certification, or have not been certified, for up to and including 12 months:
	+ there are no additional requirements that must be met.
* if you have had non-practising certification, or have not been certified, for between 12 months and up to and including 36 months:
	+ at a minimum, before re-commencing practice, you must complete the equivalent of one year’s continuing professional development (CPD) activities to be eligible for recertification.
* if you have had non-practising certification, or have not been certified, for more than 36 months:
	+ you are required to provide a plan for professional development to the Board for consideration for recertification.

### Special circumstances

All certified individuals are required to meet the CPD requirements. However, individuals may request a temporary waiver, reduced CPD requirement or an extension of time to complete CPD requirements if they are experiencing exceptional personal or professional circumstances.

A written request must be submitted to the Scheme for consideration by the Committee. Professional or personal exceptional circumstances include, but are not limited to: prolonged illness, family obligations and circumstances, financial or other hardship, and career transition. An extension of time shall not relieve the individual of the responsibility for completion of the CPD requirements.

#### Action required:

* Working group to be established to finalise initial proposed points and activity framework, using existing known CPD patterns of activity as a resource for assessing potential feasibility
* Establish a database to enable collation and analysis of first round CPD activity reporting and survey data on CPD cost and accessibility as well as demand for specific types of CPD for both scientists and technical officers
* Working group to finalise the part-time and leave policies outlined above, potentially as part of the beta testing phase.

## 9. Sanctions

Given that compulsory participation is not a feasible option for the proposed certification scheme now, the primary purpose of sanctions will be to protect the credibility of the scheme to ensure all stakeholders (including end users) can be assured that certified members are appropriately competent.

The following set of assumptions should inform the proposed sanctions:

* certification will demonstrably lead to reducing risks to the health of the public
* there may undoubtedly be individuals who will attempt to become (or remain) certified through dishonest means (e.g. they may not be capable of gaining and/or keeping certification and will attempt to falsify documents or requirements)
* certification will apply to those in current employment (but could be voluntarily suspended if the person temporarily leaves the workforce)
* sanctions such as permanent removal are likely to be extremely rare events – nevertheless, they need to be defined and agreed.

### Types of sanctions

Protecting the integrity of the scheme involves primarily only ensuring that certified workers are competent, i.e. performing their work to the standards of their level of certification.

Sanctions could be applied at three levels:

1. certification not granted (upon initial certification or recertification application)
2. temporary suspension of certification
3. permanent removal of certification.

A process for the removal of certification from an individual would need to be implemented. This would be to manage incidents where an individual has practised in a negligent manner occasioning patient harm or who may be deemed unsuitable for certification as per the requirements.

Sanctions would be applied and managed through one of the following instances:

1. random audit as part of the initial certification and recertification processes – this could be an audit of competency assessments of between 5% and 10% of scheme members
2. notification of misconduct – the Certification Board becomes aware of an incident of proven misconduct[[21]](#footnote-22) of a certified member (e.g. through a Healthcare Complaints Commission) therefore the Board would be obliged to recognise and act upon the charge[[22]](#footnote-23)
3. permanent removal from the certification scheme would require unanimous agreement by the Certification Board
4. appeals process – a member may appeal a sanction and apply for recertification, unless permanent removal has been applied.

There was strong agreement from the Delphi Conference process that permanent removal could have a significant impact on an individual’s future employability; therefore, it would be applied for serious breaches only, with temporary loss being the most likely sanction to be applied. A robust appeals process will be critical for the scheme yet, ultimately, the impact and ramifications of the sanction will be dependent on the credibility and acceptance of the scheme by individuals and employers. 87% of Delphi conference participants supported the proposition that employers should only be informed if an individual’s certification was removed on the basis of a proven or highly likely serious quality issue or suspicion of a criminal offence. There was little support for publication of certification removal details in any form.

The most appropriate governance structure for applying sanctions would be the governing board of the scheme as they have overarching responsibility for the scheme and will make the final decision about a sanction. To ensure transparency and integrity it may be useful to form a panel or small group could be formed, as necessary, to review the case and provide recommendation to the board. The arrangements for sanctions will continue to need reflection and debate as the final detail of the certification scheme is elaborated over the course of the preparation phase.

#### Action required:

* The structures for how sanctions should be managed should be considered and included as part of finalising the governing body’s Constitution and Bylaws
* Finalising the detail of sanctions to be applied should be a priority development activity once the scheme is operational
* Full application of the scheme’s sanction process is anticipated to occur from the second round of recertification which is scheduled to commence in July 2026.

## 10. Cost of participation

### Cost of entry to the scheme

The cost of entry[[23]](#footnote-24) to the proposed certification scheme should be kept relatively low to maximise the proportion of the potential workforce who would be prepared to enrol in the scheme. But the cost level does not need to be at a “bargain basement” level because it is anticipated that the inherent value of the scheme will be promoted within the profession and is likely to be widely recognised. A tax-deductible annual fee of between $300 per annum was the mean point of fee levels suggested by stakeholders. This is broadly consistent but at the lower end of the fee scales of comparable certification schemes.

The proposed certification scheme will only be sustainable if sufficient income can be generated to support the required workload of administering the scheme. The agreed objective is to establish a cost structure that would allow the scheme to stand alone but workshop participants acknowledged that there are many unknown factors at this early stage of the scheme’s development. A fee structure should be formulated in consideration of the following factors:

* simple and transparent system
* senior and/or clinical scientists, if included in future as proposed, may require a more sophisticated assessment regime and this may suggest a slightly higher fee level (e.g. $400 per annum initially, tax deductible)

Based on these considerations, the following fee structure was agreed for the proposed initial Scheme applicants from 1 July 2020 when the Scheme is due for its official full launch.

| Certification level | Initial certification fee | Recertification fee (3 yearly) |
| --- | --- | --- |
| Scientists | $350 | $300 |
| Technical Officers | $300 | $250 |

### Cost of re-certification

The process of re-certification would not require re-assessment of entry qualifications, but stakeholder discussions have determined that the overall process for recertification assessment would be relatively similar. Additional infrastructure would not be required, but the costs and resources that would be required for the re-certification process would include general administrative (e.g. communication with members, management of databases, etc.) and the costs associated with the assessment and auditing activities. Even if the scheme can attract voluntary assistance with those activities, funding would be required to support travel and meeting costs. For these reasons, a cost for recertification has been proposed that is like that of the initial certification process.

### Estimated financial viability of the scheme

The above proposed payment schedule can be used to form an estimate of the initial Certification Scheme income. Based on a 2011 study of the workforce in Australian medical pathology laboratories (Ridoutt et al., 2011) and a 2010 survey of the workforce (Urbis, 2010), it is estimated there are at least 7000 medical scientists and 3000 technical officers currently employed in the medical scientific workforce. Assuming an initial participation uptake rate for the Scheme of 30% to be achieved by the end of the first 3 years (the most popular estimate of the Workshop participants), a crude income estimate for the Scheme by 2023 could be calculated as follows:

| Scientists | 7,000 | x | $350 x 0.3 | = | $735,000 |
| --- | --- | --- | --- | --- | --- |
| Technical Officers | 3,000 | x | $300 x 0.3 | = | $270,000 |
| **Estimated initial total scheme income (3-year cycle)** | = | **$1,005,000** |

Based on a rate of just under half of the initial cost of entry into the scheme, income from ongoing participation in the scheme, or re-certification, could be similarly calculated as follows:

| Scientists | 7,000 | x | $300 x 0.3 | = | $630,000 |
| --- | --- | --- | --- | --- | --- |
| Technical Officers | 3,000 | x | $250 x 0.3 | = | $225,000 |
| **Estimated ongoing total scheme income (3-year cycle)** | = | **$855,000** |

Thus, in the first three years of operation given the proposed cost of certification and assumptions about uptake, the revenue would be approximately $1.005 million, giving an annual budget of approximately $335,000. An Excel spreadsheet model has been developed as part of the Implementation Plan to allow on-going testing of the budget situation.

In order to underline its independence, the most desirable outcome would be for the scheme to become viable as a stand-alone entity within a short period of time. In the absence of any other form of available financial support and during the establishment period, initial subsidisation by professional associations and societies might need to be sought to ensure initial uptake and financial viability of the scheme. This subsidisation could take the form of “seeding” money to support the establishment of governance and operational structures of the agreed scheme. Those providing ‘seed’ funds would become shareholders in the certification governance arrangement (see Governance Section).

However, if needed, further support for the scheme might be achieved through partnership with stakeholder organisations via a combination of:

1. An ongoing annual fee proportional to the number members; associations pay a fixed portion of their fees to the scheme on an annual basis (not a preferred option – the key aim is to establish a certification scheme that will be self-supporting financially)
2. In-kind support from associations in one or more of the following ways:
* Administrative, IT, payroll and Human Resource functions
* Infrastructure support such as low-cost office spaces, meeting rooms,
* Marketing and advertising of the scheme through association communication channels, conferences and workshops
* Volunteer assessors and auditors
* Board representation
* Academic input and support e.g. support to define competency requirements and guidelines.

The cost of participation in the scheme has been set at a low level (including certification fees being paid each 3-year period) compared to the rates of annual fees paid by the majority of other health professions (and professional groups more broadly). The modest proposed entry and recertification fees for both scientists and TOs ($350 for initial entry and $300 for recertification each 3 years) reflect a recognition that scheme participants may also be paying for one or more other professional memberships, some of which include the cost of a CPD monitoring system. Recertification fees are similar to initial certification fees because the anticipated assessment processes will be similar and therefore require a similar amount of effort on the part of the certifying body for both professional groups. However, the reportedly current low level of CPD options taken up by TOs and small number of relevant professional groups suggests that it may be appropriate for the certifying body to focus on building up a suite of suitable CPD activities that can be easily and cheaply accessed by TOs throughout Australia.

### Proposed fee discounts

To ensure high participation in the scheme the potential for discounting the fees has been considered. Discounts might apply for (1) early participation, particularly as a beta tester pre the formal launch of the scheme in 2020 (2) to consider multiple fee requirements e.g. certification + CPD scheme enrolment + professional association membership. Professional associations themselves may further contribute to the discount by offering lower membership fees to individuals who participate in the certification scheme and a CPD scheme.

Proposed discount offers are outlined below.

| **Entry Phases** | **Scientists** | **Technicians** | **Period of coverage** |
| --- | --- | --- | --- |
| **1 Sept 2019 – 12 January 2020** |
| Beta testers | $200 | $150 | From enrolment to 30 June 2023 |
| CPD scheme-enrolled | $165 | $115 |
| **13 January 2020 – 30 June 2020** |
| Early entry | $250 | $200 | From enrolment to 30 June 2023 |
| CPD scheme-enrolled | $215 | $165 |
| **1 July 2020 –30 June 2023** |
| Full entry fee | $350 | $300 | Rolling – from date of enrolment to 3-year anniversary of enrolment |
| CPD scheme-enrolled | $315 | $265 |
| **From 1 July 2023 to 30 June 2026** |
| Recertification | $250 | $200 | From enrolment to 30 June 2023 |
| New enrolments | $350 | $300 | Three years from date of certification  |

#### Action required:

* Final fees and discounts to be confirmed by the Interim Board.

# Implementation phases

## Overview of the Implementation Plan

A commencement date for the Certification Scheme was set by stakeholders at 1 July 2020. Between now (April 2019) and then two distinct phases of activity are planned, the first phase to set up the governing arrangements for the Scheme and prepare the mechanisms for promoting and managing the Scheme. The second phase will begin testing the mechanisms and identifying and eliminating any implementation problems prior to the full commencement of the Scheme in 2020.

Although there has been significant input from representatives of all the participating professional associations, the implementation plan will continue to need finessing by the governance group throughout the coming 14 months prior to the formal commencement of the scheme.

## Phase 1: First 6 months from end of May to September 2019

1. **Activities to be undertaken**
* Company to manage the Certification Scheme legally established and accounts set up
* Meeting of company members to approve the constitution and elect the inaugural Board of Directors
* Board, advisory committees and working parties commence operation
* Web site development contracted and constructed including mechanisms for online applications for certification
* Web content maximised – including, for example, collated existing CPD access options
* Working parties establish database of accepted qualifications for Scheme entry
* Concerted promotion and marketing campaign to maximise enrolment
* Registrar and Administrative Officer positions advertised, recruited and filled by 1 September 2019
1. **Who will do the work?**
* Interim Board members (or their Nominated Representative/s)
* Other potential Member representatives for both workshops and working groups (self-funded)
* Volunteer working groups
* Donated association staff time for specific activities
* Outsourced specialist goods and services as required e.g. legal and financial advice for establishment of the company and creation of branding, website and relevant databases (to be funded from organisational donations/advances and early entry applicant fees).
1. **How will it be paid for till September 2019?**
* Member fees to set up the company
* Donation of office/meeting room space and utilities expenses
* Donation of additional staffing hours as needed
* Purchase of specific projects – each project paid for by a volunteer member organisation (or consortium) and acknowledged as an official contribution to the scheme
* Volunteer labour (e.g. working group contributions)
* Donation of travel/accommodation requirements for meeting/workshop attendance
1. **Budget requirements - costs to be estimated considering in-kind contributions**
* Finalise constitution and financial structures for the company
* Website design and creation
* Database/portal creation and initiation
* ISP hosting and IT support
* Organisation and facilitation of shareholder workshops
* Legal and financial advice for setting up company and associated fees and charges
* Create online access and downloadable logbook (editable PDF form)
* Board elections, establishment of committees and Standing Advisory Committee invitations
* Staff and volunteer position descriptions drafted

## Phase 2: From October 2019 to 30 June 2020

1. **Activities to be undertaken**
* Recruit and enrol Scheme mechanism ‘beta testers’ - includes ‘early adopters’
* Commence assessment of submitted information (volunteer assessors in the first instance).
* Identify Scheme mechanism problems and resolve
* Web updating and maintenance
* ISP, telecommunications, web hosting
* Accountant fees
* Additional staff to be employed over time as required, income allowing - includes casual staff to assist at peak times
1. **Who will do the work?**
* Registrar and Admin Officer – fulltime employees
* Volunteer labour (e.g. working group contributions)
1. **How will it be paid for?**
* Beta tester application fees (see details of this later in the Plan)
* Member enrolment fees from 1 September 2019.
* Donation of office/meeting room space and utilities expenses
* Company Member donation of additional staffing hours as needed

Phase 3 of the Implementation Plan commences when the Scheme officially goes live on the 1st July 2020. This phase will be for 3 years until the first batch of re-certifying certification participants commence and more rigorous certification and re-certification process are introduced. At the end of this Phase 3 an evaluation will be undertaken.

A draft timetable is provided with more details of the implementation process in the next few pages.

**Draft Implementation Activity Plan**

| **Area of activity** | **Who?** | **2019** | **2020** |
| --- | --- | --- | --- |
| M | A | M | J | J | A | S | O | N | D | J | F | M | A | M | J | J | A | S | O | N | D |
| **Phase 1: May to September 2019** |  |  |
| **Initiation of implementation phase and formalise organisational structure** |  |  |
| Proposed official certification scheme start date |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Initiate implementation steering arrangements | Certification Project Coordination Group (PCG) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Set up initiation fund (cash and in-kind support)  | PCG and intending Members |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Engage legal/management consultancy advice on the establishment of the company structure for the new certification body, using the draft Constitution as a basis | PCG; outsourced advice |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Commence process of establishing formal company governance | PCG |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Once agreed, initiate necessary payments and registrations required to establish the company governance infrastructure | Interim management committee |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Set up bank accounts and payment arrangements (in and out, including secure payments via website) | PCG; outsourced finance support |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Initiate Member subscription payments to establish Inaugural Board of Directors | Intending Members; outsourced legal and finance advice |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Board commences operation | Interim Board |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Core executive committee (meets every month) | Interim executive committee; volunteer secretariat |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Advisory group of other shareholders (meets every 3 months - facilitated sessions) | Interim Board; Standing Advisory Group;volunteer secretariat; outsourced facilitation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Beta-test the payment arrangements | Interim Board; Communication working group; outsourced technical support |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Refining detail of scheme content and structure phase** |  |  |
| Establish working group to work through the detail of how to assess Technical Officer qualifications and CPD activities - bi-monthly meetings | Volunteer Member working group and relevant invited stakeholders |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Set up database for collecting info on formal qualifications  | Qualifications working group; outsourced technical support |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Set up database for recording of CPD and workbook data lodgement | CPD working group; outsourced technical support |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Engage web designer to establish scheme website  | Communication working group; outsourced service |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Initiate secure e-data storage and ISP account contracts for web access and email contact | Interim executive committee; outsourced service |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Beta version website goes live and is monitored | Outsourced service; communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Web updating | Outsourced service; communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Commence engagement with membership**  |  |  |
| Initiate and conduct work on collating best practice competency assessment tools and processes to support implementation of the certification scheme (scale of this work will depend on funding available - possible QUPP project activity) | Interim Board; Standing Advisory Committee; outsourced facilitation and project work if funds available |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Commence newsletter publication schedule and establish mailing list, using project mailing list and standard association communication channels | Communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Develop marketing strategy for phased implementation | Outsourced service; communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bi-monthly newsletter updates | Communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Phase 2: October 2019 to June 2020** |  |  |
| **Commence work on enrolling members phase** |  |  |
| Invite participation of “beta-tester” registrants for assessment of qualifications, certificates of competence and CPD activity | Communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Commence enrolment of beta-tester registrants and trouble-shoot any identified issues | Qualifications working group; CPD working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Identify problems with processing applications and trouble shoot |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Establish mailing list/wiki site for engagement with volunteer assessors and maintain regular contact | Communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Staff recruitment phase** |  |  |
| Establish core HR policies and reporting arrangements | Interim executive committee’ Interim Board |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Recruit Registrar (at end of previous phase) | Interim Board |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Recruit Administrative Officer | Interim Board; Registrar |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Commence recruitment of volunteer assessors | Assessor working group; communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hold workshop for volunteer assessors | Interim Board; Registrar; assessor working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Phase 3: July 2020 to June 2023** |  |  |
| **Scheme commencement phase** |  |  |
| Announce the commencement of the scheme as per marketing strategy | Interim Board; Communication working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| First post-beta (full certification) applications are received and logged | Registrar; Admin Officer; qualifications and CPD working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Assessments commence using employer / supervisor provided tools | Chief Executive; other staff; qualifications and CPD working group; assessor working group |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Company accounts are audited | Interim Board; Registrar; appointed auditor |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Call Annual General Meeting and conduct process of election and appointment of company directors | Interim Board |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Initiate evaluation of Scheme (2023) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

# Discussion of project outcomes

## Achievement of objectives

A number of tasks were specified as required to be completed during the course of the project. Table 4 below summarises the achievement outcome for each of these tasks.

Table 4: Summary of achievement of specified project tasks

| **Project task** | **Achievement status** | **Comment** |
| --- | --- | --- |
| Establish a Project Steering Group | Completed | The PSG met at all critical times during the project and were a critical devise for (1) maintaining relevance of the project outputs and (2) engendering ownership of the final product |
| Develop a research plan (activity plan) | Completed |  |
| Undertake a literature review and case study level analysis | Completed | See Discussion Paper. This step to create a strong evidence base was crucial to initial consultation processes and started those consultations with a high level of credibility |
| Explore affordability and sustainability of potential models | Partly | A single model was identified quite early in consultations so all the research effort, including financial sustainability, were focused on that model |
| Undertake stakeholder analysis | Completed | All key stakeholders (over 20) were able to be identified and their interests ascertained |
| Effectively engage with stakeholders | Completed | The workshop, Delphi Conference and individual stakeholder consultations proved very powerful and effective. Only some of the employee representative bodies remained officially slightly aloof from the process but appropriate ‘delegate’ level engagement was strong |
| Review the Competency standards Framework | Completed | Testing with PAC confirmed the Framework’s validity |
| Ensure agreement of participating professional organisations | Completed | All major associations are signed up for the implementation (> 60%). Several smaller groups are interested in being part of the Scheme governance arrangements  |
| Prepare project products | Completed | Discussion PaperSeveral versions of a Position PaperImplementation Plan |

## Problems and delays

For such a long project there were remarkably few problems. The project was scheduled to be conducted from June 2017 until 30 April 2019, so the project was only one month over schedule. The slight delay was to accommodate additional consultation processes, in particular an extra workshop (supported by the Department) to assess the outcome of the Delphi Conference process and reach final agreement on the Position Paper before going to individual professional associations). The benefit of this additional consultation was significant.

In terms of problems, there was only one significant stakeholder who did not wholeheartedly support the notion and the actual prospect of a certification scheme. Australian Pathology (AP), the peak industry body that represents the private pathology organisations, raised concerns during the course of the consultation process (in which they gratefully participated fully) about the need for the scheme and any cost burden that might fall on to employers. These concerns were subsequently also raised with the Department.

As noted above AP never left the processes of consultation. On the other side of the coin, the public sector employers, including their representative body, were extremely supportive of the certification scheme concept and the practical way it was evolving. Discussions with senior people within individual private pathology companies indicates that private sector employers may adopt a different stance to the industry body as the scheme is implemented, particularly if the benefits of the scheme begin to become obvious and the feared degree of cost burden does not eventuate.

## Overall assessment

Against a background of past let-downs and fragmentation in the quest for certification / registration of the medical scientific workforce, this project proved a considerable success.

All the tasks required were completed, but more importantly the central outcome of an agreed Certification Scheme was achieved. That such a strong consensus around the proposed scheme, its governance arrangements, its financial mechanisms, its implementation processes, has been garnered is a testament to the willingness of many stakeholders to subjugate some of their own interests in search of a commonly desired goal.

The Scheme could not be in better hands.

# References

AICD guidance:

<http://aicd.companydirectors.com.au/resources/all-sectors/roles-duties-and-responsibilities/governance-of-not-for-profit-organisations?no_redirect=true>

<http://www.companydirectors.com.au/~/media/cd2/resources/director-resources/nfp/pdf/nfp-principles-and-guidance-131015.ashx>

<https://aicd.companydirectors.com.au/-/media/cd2/resources/director-resources/director-tools/pdf/05446-3-1-mem-director-tools-gr-number-of-directors_a4-web.ashx>

<https://aicd.companydirectors.com.au/-/media/cd2/resources/director-resources/director-tools/pdf/05446-3-11-mem-director-gr-role-of-board_a4-v3.ashx>

<https://aicd.companydirectors.com.au/~/media/cd2/resources/director-resources/director-tools/pdf/05446-3-6-mem-director-gr-advisory-boards_a4-web.ashx>

Alpha Scientists in Reproductive Medicine. (2015). The Alpha Consensus Meeting on the professional status of the clinical embryologist: proceedings of an expert meeting. *Reproductive BioMedicine Online, 30*, 451–461.

American Society for Clinical Pathology (2018). *US Credential Maintenance Program Booklet*. American Society for Clinical Pathology: Illinois. Accessed online 16 April 2018 at <https://www.ascp.org/content/docs/default-source/boc-pdfs/boc-stay-credentialed-general-cmp-pdfs/ascp-cmp-us-booklet-final-web.pdf?sfvrsn=8>

APRN. (2008). *Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education.* Advanced Practice Registered Nurses.

Ayres, R.E., Scheinthal, S., Gross, C. and Bell, E.C. (2009). Osteopathic Specialty Board Certification. *J Am Osteopath Assoc, 109*, 181-190.

Australian Skills Quality Authority, *Appendix 2—Standards for Registered Training Organisations (RTOs) 2015* <https://www.asqa.gov.au/standards/appendices2/appendix-2>

Chanduvi, D.G., de los Ríos Carmenado, I., Gajardo, F.G., & Torres, J.G. (2011). International models of professional competence certification: a characterization of eight models. *Selected Proceedings 14th International Congress on Project Engineering. AEIPRO. International Project Management Association (IPMA).* Pg: 51-68.

Chung, K.C., Clapham, P.J., and Lalonde, D.H. (2011). Maintenance of Certification®, Maintenance of Public Trust. *Plast Reconstr Surg., 127*(2), 967–973.

COAG (2017) *Independent Review of Accreditation Systems Within the National Registration and Accreditation Scheme for Health Professions – Draft Report*. Australian Government, Canberra - <https://www.coaghealthcouncil.gov.au/Portals/0/Accreditation%20Review%20Draft%20Report_U.pdf>

Culley, D.J., Sun, H., Harmann, A.E., Warner, D.O. (2013). Perceived value of Board certification and the Maintenance of Certification in Anesthesiology Program (MOCA®). *Journal of Clinical Anesthesia, 25*, 12-19.

Gourley, D. R., Fitzgerald Jr, W. L. and Davis, R. L. (1997). Competency, board certification, credentialing and specialization: who benefits? *American Journal of Managed Care, 3*(5), 795-807.

## References

Howanitz, P., Valenstein, P and Fine, G. (2000) Employee competence and performance-based assessment. *Arch Pathol Lab Med*, 124:195-xx

Ingvarson, L. (2014). *Professional certification for accomplished principals: directions for Australia.* Adelaide: Principals Australia Institute.

Ingvarson, L. (2017). Developing a professional certification system for school principals: The Principals Australia Institute certification project. *Research Conference*, (pp. 55-60).

Jha, S. (2015). Point: Twin Dogmas of Maintenance of Certification. *Journal of the American College of Radiology*, 430-433.

Knapp, J. (2000) *Designing Certification and Accreditation Programs*. From The Association Educator’s Toolkit. American Society of Association Executives

Mackinnon, A.C., Wang, Y.L., Sahota, A., Yeung, C.C. and Weck, K.E. (2012). Certification in Molecular Pathology in the United States. *The Journal of Molecular Diagnostics, 14*(6), 541 - 549.

Malone, B. (2017) *Competency Assessment: Does the New CLIA Guidance Mean Big Changes? Clinical* Laboratory News, June <https://www.aacc.org/publications/cln/articles/2013/june/competency>

Matillon, Y., LeBoeuf, D. and Maisonneuve, H. (2005). Defining and assessing the competence of health care professionals in France. *J. Contin. Educ. Health Prof*., 25: 290–296. doi:10.1002/chp.43.

Medical Laboratory Science Board (2015) Code of Competencies and Standards for the Practice of Medical Laboratory Science, Medical Laboratory Science Board, New Zealand - <http://www.mlsboard.org.nz/assets_mlsb/Uploads/Documents/Code-of-Competencies-and-Standards.pdf>

New Zealand Institute of Medical Laboratory Scientists (2018). CPD Programme overview. Accessed online 30 April 2018 at <https://www.nzimls.org.nz/cpd.html>

NPAAC Requirements for Medical Pathology Services (2013) - [http://www.health.gov.au/internet/main/publishing.nsf/Content/21B7F24866EF1DEECA257C2A001EC403/$File/Reqmts%20for%20Medical%20Path%20Services.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/21B7F24866EF1DEECA257C2A001EC403/%24File/Reqmts%20for%20Medical%20Path%20Services.pdf)

NCSBN. (2008). *Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education. NHS (2005) A career framework for Healthcare Scientists in the NHS*. Department of Health, November 2005 [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_412320 5](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_412320%205)

NZ Medical Laboratory Scientist Code of Ethics – <https://www.mscouncil.org.nz/assets_mlsb/Uploads/MSC-Proposed-Code-of-Ethics3.pdf>

https://www.ourcommunity.com.au/management/view\_help\_sheet.do?articleid=2104

Perlstein, L., Hoffmann, R.L., Lindberg, J. and Petras, D. Addressing Barriers to Achieving Nursing Certification. *Journal for Nurses in Professional Development, 30*(6), 309-315.

Pilbeam, V., Badrick, T. and Ridoutt, L. (2013) *Best practice pathology collection* for Department of Health, Canberra, Australia.

## References

Principals Australia Institute. (2013). *Proposal - Certification of Principals, Discussion Paper 1: March 2013.* Adelaide: Principals Australia Institute.

Ridoutt, L., Pilbeam, V., and Bagnulo, J, (2011) *Career Structures and Pathways for the Scientific Workforce in Medical Pathology Laboratories –* ***Final project report*** for the Department of Health and Ageing, Canberra Australia. <http://humancapitalalliance.com.au/wp-content/uploads/2016/03/Final-Report-Career-Structures-and-Pathways-for-scientific-workforce-in-medical-pathology-laboratories-final.pdf>

Rowe, G. and Wright, G. (1999): The Delphi technique as a forecasting tool: issues and analysis. *International Journal of Forecasting, Volume 15, Issue 4*: 353–375.

Royal Australian College of General Practitioners (2016). QI & CPD Program: 2017–19 triennium handbook for general practitioners. East Melbourne, Vic: RACGP - <https://www.racgp.org.au/education/qicpd-program/>

RTAC accreditation framework - <https://www.fertilitysociety.com.au/wp-content/uploads/2017-RTAC-ANZ-COP-FINAL-1.pdf>

PAC (2009), Scope of Practice and Competency Framework for Australian Medical Scientists

Stanford, D., Cowles, C. and Ridoutt, L. (2017) *Discussion Paper: National Certification Scheme for Medical Laboratory Scientists*. Australian Institute of Medical Scientists, Brisbane. <http://humancapitalalliance.com.au/wp-content/uploads/2018/04/Medical-Laboratory-Scientific-Workforce-Certification-Discussion-Paper-November-2017.pdf>

Termuhlen, P.M., O-Yurvati, A.H. and Stella, J.J. (2016). Requirements for Certification in Surgery: A Comparison of the American Board of Surgery and the American Osteopathic Board of Surgery. *J Am Osteopath Assoc., 116*(10), 676-682.

UK Biomedical Scientist Code of Conduct - <https://www.ibms.org/my-ibms/code-of-conduct/>

Urbis (2011), Survey of the Pathology Workforce Survey. Department of Health and Ageing, Canberra - <https://www.aims.org.au/documents/item/197%20p.%2011>

Vervaart, P. (2016) *Review of the APACE CPD Scheme*. Prepared by LabMed Consulting for AIMS

VET Certificate III in Pathology (blood/specimen collection) competency framework - https://training.gov.au/training/details/HLT32612

VET Technical Officer competency framework - https://training.gov.au/Training/Details/MSL50116

Wang, T. A. (2011). A competency framework in cardiothoracic surgery for training and revalidation — an international comparison. *European Journal of Cardio-thoracic Surgery, 40*, 816-825.

# **Appendix A: Comparison of professional certification arrangements**

| Profession | Point of entry | Competency basedFramework (Y/N) | CPD – competency based(Y/N) | More than one level of certification(Y/N) | Annual fee |
| --- | --- | --- | --- | --- | --- |
| Dietitian | Accredited degree | Yes | Yes | No | $708 |
| Audiologist(certified) | Accredited masters degree + one year internship | No | No | No | $480 |
| Speech pathologist | Accredited degree | Yes | No | No | $535 |
| Occupational therapist (OT) | Accredited degree | World OT standards framework | No | No | $650 |
| Social worker | Accredited degree | No | No | Yes | $697 |
| Exercise scientist | Min. Level 7 AQF | Yes | Yes | Yes  | $358  |
| Sonographer | Postgraduate diploma or above | No | No | Yes  | $470 |
| Orthotists & Prosthetists  | Level 7 AQF in both prosthetics and orthotics | Yes | No | No | $644 |
| Cardiac perfusionist(certified) | Fellowship exam (joint Colleges of Surgeons and Anaesthetists Board) | No | No | No  | $305 |
| Physiotherapist | Accredited degree | No | No | No  | $768 |
| Optometrist | Accredited degree | No | No | No | $300 |
| Health Informatician | Graduate member – relevant degree and current HI employmentFull member – relevant degree + min. 3 years HI employment | Yes | Yes | Yes | $360 |
| Genetic counsellor | Masters degree in addition to a relevant degree, such as genetics, psychology, social work, law, nursing/ midwifery, science etc., plus HGSA certification process (case observation, log book, long cases, CPD) | Yes | Yes | No | $338, including MOPS (CPD) |
| Medical Radiation Practitioner | Accredited degree | Yes | No | Yes | $185 plus $150-200 pa for radiation licence per jurisdiction |
| Lawyer | Accredited degree plus specified Practical Legal Training against set requirements/competencies (now usually a 6 month graduate professional qualification - “Legal Workshop” - Level 8 AQF qual)  | Yes | Yes | No | $868 or $798 |
| Engineer | Accredited degree plus 3 years of F/T employment for Full Member and/or Chartered Engineer | No | No  | Yes | 4th year out - $507 plus $30-50 for technical society membership |
| Architect | Accredited degree (or other approved pathway); minimum 12 month’s employment (3,500 hours)plus logbook for documenting progress against the competencies plus written examination plus interview | Yes | Yes | Yes | Registration (e.g. NSW $1,100),AIA annual fee - $1,030  |
| Landscape architect | Accredited degree plus minimum 2 yrs full-time (or equivalent) employment as a LA; formal mentorship with assessment against 13 competency areas; formal oral interview assessment. | Yes | No  | Yes | $611 (plus $800 joining fee) |
| Accountant | Anyone providing accountancy services to the public must hold a Professional Practising Certificate (PPC)PLUSIPA – accredited degree plus fee-paying post grad qualification required (Deakin University)orCPAA – accredited degree plus CPA exam plus employment (alternative pathway – additional Foundation Exam prior to CPA exam) | No | No | No | PPC ($557)CPAA - $180 joining fee plus $720 pa |
| Medical science Professions | **Point of entry** | **Competency based****Framework (Y/N)** | **CPD – competency based****(Y/N)** | **More than one level of certification****(Y/N)** | **Annual fee** |
| New Zealand | Accredited degree + provisional supervised registration (3-24 mths)(overseen by the NZ Medical Laboratory Science Council) | Yes | Yes | Yes | $350 registration fee, plus approx. $300 re-certification fee |
| United Kingdom | Accredited degree plus approved Training Portfolio (completed over 3-6 years, depending on initial qualification) | Yes | No | Yes | ~$300 |
| South Africa | Accredited degree plus 12 months structured supervised practice plus entrance examination | No | No | Yes | $118 - $123 |
| Republic of Ireland | Accredited degree **or** degree with assessed relevance + 1000 hours supervised training + 2 years work in a laboratory |  |  | Yes | 150 Euros |
| United States (common term for medical scientists is Medical Technologist) | Range of requirements but 13 States require licensing (various requirements, inc suitable degree, on the job training etc). Certification is offered by several providers - entrance examination required – not compulsory but appears to be influential in job market. | Yes | No | Yes | $135 to $530 |
| Canada(differs by province)(common term for medical scientists is Medical Laboratory Technologist) | Complete a Canadian Medical Association accredited course in medical laboratory technology, diagnostic cytology, clinical genetics technology or medical laboratory assistant PLUS pass the relevant Canadian Society for Medical Laboratory Technology examination (then certification-eligible) | Yes |  |  | $172 inc. public liability insurance plus $720 exam fee or $1570 prior learning assessment fee |

# Appendix B – Australian Quality Framework: Key Skills by Level

| **AQF Level** | **Skills required** |
| --- | --- |
| Level 3 / 4 | Workers at this level will have a range of cognitive, technical and communication skills to select and apply a specialised range of methods, tools, materials and information to:* complete routine activities
* provide and transmit solutions to predictable and sometimes unpredictable problems.

At level 4, need to be able to deal with some non-routine activities |
| Level 5 | Workers at this level will have a broad range of cognitive, technical and communication skills to select and apply methods and technologies to:* analyse information to complete a range of activities
* provide and transmit solutions to sometimes **complex** problems
* transmit information and skills to others
 |
| Level 6 | Workers at this level will have a broad range of cognitive, technical and communication skills to select and apply methods and technologies to:* analyse information to complete a range of activities
* **interpret** and transmit solutions to **unpredictable** and sometimes complex problems
* transmit information and skills to others
 |
| Level 7 | Workers at this level will have well-developed cognitive, technical and communication skills to select and apply methods and technologies to:* analyse and **evaluate** information to **complete** a range of activities
* **analyse, generate** and transmit solutions to unpredictable and sometimes complex problems
* transmit knowledge, skills and ideas to others
 |
| Level 8 | Graduates at this level will have advanced cognitive, technical and communication skills to select and apply methods and technologies to:* analyse **critically**, evaluate and transform information to complete a range of activities
* analyse, generate and transmit solutions to complex problems
* transmit knowledge, skills and ideas to others
 |
| Level 9 | Workers at this level will have expert, specialised cognitive and technical skills in a body of knowledge or practice to independently:* analyse critically, reflect on and synthesise complex information, problems, concepts and theories
* research and apply established theories to a body of knowledge or practice
* interpret and transmit knowledge, skills and ideas to specialist and non-specialist audiences
 |
| Level 10 | Workers at this level will have expert, specialised cognitive, technical and research skills in a discipline area to independently and systematically:* engage in critical reflection, synthesis and evaluation
* develop, adapt and implement research methodologies to extend and redefine existing knowledge or professional practice
* disseminate and promote new insights to peers and the community
* generate original knowledge and understanding to make a substantial contribution to a discipline or area of professional practice
 |

1. See for instance membership of the National Alliance of Self-Regulating Health Professionals (NASRHP) … http://nasrhp.org.au/ [↑](#footnote-ref-2)
2. This aim is taken word for word from the QUPP funding agreement schedule. As will be noted later in this report the aim actually achieved was broader in scope in several key areas, particularly in regard to ‘pathology’ and ‘workforce’, than the original aim prescribed. [↑](#footnote-ref-3)
3. Human Capital Alliance (2011) *Career Structures and Pathways for the Scientific Workforce in Medical Pathology Laboratories – Final Project Report.* Report commissioned by the Department of Health and Ageing, July [↑](#footnote-ref-4)
4. Note that during the course of the project the word pathology was discarded in regard to terminology in the certification scheme in order to be inclusive a broader range of medical scientific workers engaged in laboratories. [↑](#footnote-ref-5)
5. Later replaced by Mr Peter Ward, Incoming President, AACB [↑](#footnote-ref-6)
6. Also the CEO for HGSA [↑](#footnote-ref-7)
7. Stanford, D., Cowles, C. and Ridoutt, L. (2017) *Discussion Paper: National Certification Scheme for Medical Laboratory Scientists*. Australian Institute of Medical Scientists, Brisbane [↑](#footnote-ref-8)
8. Stanford, D., Cowles, C. and Ridoutt, L. (2018) *Position Paper: National Certification Scheme for Medical Laboratory Scientists*. Australian Institute of Medical Scientists, Brisbane. [↑](#footnote-ref-9)
9. In recent months as the details of the scheme have been consolidated and promoted more widely, other relevant professional associations have stated a keenness to be inaugural members of a certification scheme company. This includes state jurisdiction based Histotechnology Societies that recently have decided to form a national association in order to participate and contribute more fully in the implementation of the certification scheme. [↑](#footnote-ref-10)
10. This level requires further discussion – see Levels of Certification section above. [↑](#footnote-ref-11)
11. <https://www.fertilitysociety.com.au/wp-content/uploads/2017-RTAC-ANZ-COP-FINAL-1.pdf> [↑](#footnote-ref-12)
12. [https://www.aqf.edu.au/.](https://www.aqf.edu.au/) See Appendix B for a summary of the AQF levels. [↑](#footnote-ref-13)
13. The current project is not intended to endorse or promote any particular employer response in this situation but the proposed certification Scheme may offer clarity for both employers and employees to support better-targeted competency-based workplace assessment. [↑](#footnote-ref-14)
14. <https://www.aqf.edu.au/aqf-second-edition-january-2013> [↑](#footnote-ref-15)
15. As assessed by the relevant Scheme committee, panel and/or Board [↑](#footnote-ref-16)
16. This element of the assessment would be designed to test applicants’ core scientific knowledge and its application to a laboratory setting, with a focus on core competencies for professional practice. [↑](#footnote-ref-17)
17. This element of the assessment would be to demonstrate the applicant’s familiarity with and competence in laboratory practice, as endorsed by a laboratory manager or supervisor. The certifying body may wish to specify and publish key reporting elements and checklists as minimum standards for submission and this may include discipline-specific competencies as relevant to the worker and their current position. This core format could also be augmented as required by the employer to reflect specific workplace requirements. By default, the logbook format would act as a simple self-assessment tool for progress toward competence by both staff and employers. [↑](#footnote-ref-18)
18. This element of the assessment would operate (at least initially) like existing CPD programs – participants would select from and complete a range of CPD activity options to support their professional development during their conditional practice period and then compile a record of that activity for inclusion in their portfolio of evidence. Over time, and perhaps with guidance from the certifying body, CPD activity providers should be encouraged to become increasingly transparent with regard to their activities’ relevance to building professional skills relevant to the competency framework. [↑](#footnote-ref-19)
19. Australian Skills Quality Authority, *Appendix 2—Standards for Registered Training Organisations (RTOs) 2015*, accessed online 16 April 2018 at <https://www.asqa.gov.au/standards/appendices2/appendix-2>, [↑](#footnote-ref-20)
20. Taken from Medical Board ‘Recency of practice’ standard.

file:///C:/Users/carla.cowles/Downloads/Medical-Board---Registration-standard---Recency-of-practice---1-October-2016.PDF [↑](#footnote-ref-21)
21. Where that misconduct violated competence requirements of the competency framework. [↑](#footnote-ref-22)
22. Note: it was proposed that it would not be the responsibility of the Certification Board to conduct additional investigations. [↑](#footnote-ref-23)
23. Note: Discussion around entry and recertification fees assumes that these are costs that will be borne by individual workers to support their personal taxable income earning activities. On this basis, the cost of certification fees would become a tax-deductible work-related expense (“membership of a professional organisation”). [↑](#footnote-ref-24)