National Certification Scheme for Medical Laboratory Scientists

DRAFT FINAL

Position Paper

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HUMANCAPITAL Alliance

Creating workforce solutions

This Position Paper was prepared by Human Capital Alliance under the guidance of a Project Coordinating Group established and jointly convened by the Australian Institute of Medical Scientists (AIMS) and the Australasian Association of Clinical Biochemists (AACB). The Project is funded by the Australian Government Department of Health through the Quality Use of Pathology Program.

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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

Contents

A. Background and rationale for the project

Aim of the project

Initiated jointly by AIMS and AACB, and funded by the Australian Government Department of Health through the Quality Use of Pathology Program (QUPP), the aim of this project is to explore the development and structure of a national professional certification model for the medical laboratory scientist and technician workforce in Australia. Some means for assuring the quality of the pathology scientist workforce has been a long-held ambition for many in the profession. 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 are 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.

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 rationale for certification

The pursuit of certification, the detail of which will be defined more precisely later in this paper, 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.

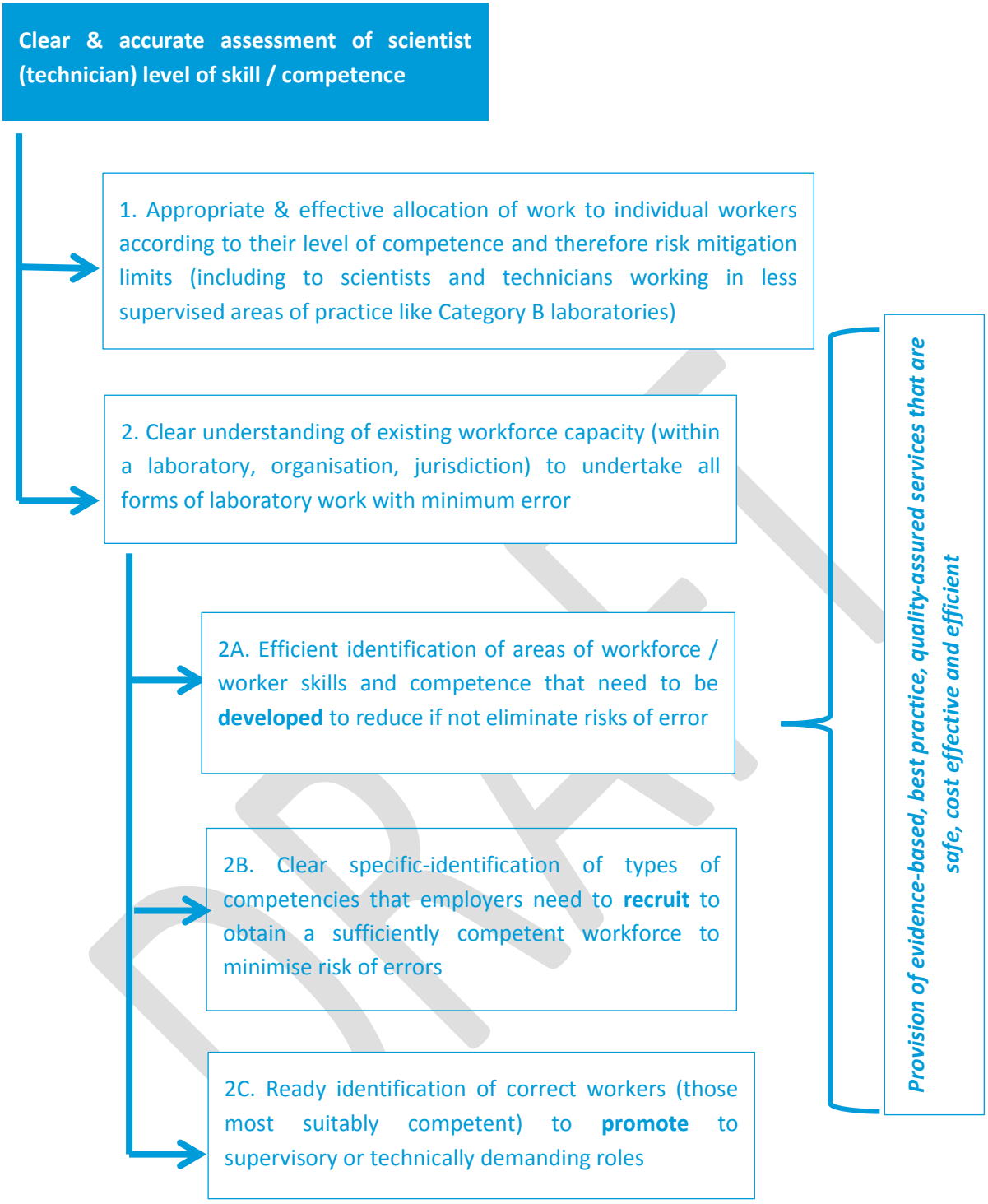

Figure 1: Proposed logic between proposed intervention and outcomes

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.

In Australia, the above logic is given some regulatory force via a process of Laboratory Accreditation (Vervaart, 2016). The National Pathology Accreditation Advisory Council (NPAAC) is a ministerially appointed Council established to advise the Australian state and territory governments on matters relating to the accreditation of pathology laboratories and the quality of pathology services. 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.

In regard to 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).

Project governance arrangements

Following over 10 years of broad stakeholder discussion about the state of the medical scientist profession in Australian pathology laboratories and a range of workforce issues, the two largest professional associations (AIMS and 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 the Australian Government Quality Use of Pathology Program (QUPP) to develop a model for establishing and implementing a certification scheme for the medical science profession. The project commenced in July 2017, jointly led by AIMS and AACB and chaired by A/Prof Tony Badrick. It has been well supported by a Project Coordination Group that includes the AIMS and AACB Presidents and CEOs, an NPAAC member representative and a Departmental representative. The HCA project team has also been guided by the Project Coordination Group.

In accordance with the commitment to inclusiveness, representatives from an additional 11 stakeholder organisations[1] have been invited to participate in a series of national interviews, surveys and workshops,

[1] Human Genetics Society of Australasia (HGSA), Australian Society of Microbiology (ASM), Fertility Society of Australia (FSA), Australian Society of Cytology (ASC), Australia and New Zealand Society for Blood Transfusion (ANZSBT), Australian Society of Immunology and Allergy (ASCIA), Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ), Australian Cytometry

assist with the drafting of positions on key topics for a certification framework, contribute to a Delphi conferencing process, and comment on draft discussion and position papers. This process of engagement (outlined in more detail below) has assisted the project to move increasingly toward agreement on a model of certification that would be appropriate for the Australian medical science profession (both current and into the medium term).

Processes informing the Position Paper

Background research

With the assistance of the Project Coordination Group, the HCA team (Lee Ridoutt, Debbie Stanford and Carla Cowles) undertook a literature search and prepared a Discussion Paper (Stanford, et al., 2017) to support stakeholder consideration of the issues around a possible certification scheme for the medical laboratory science workforce. In addition, a series of interviews have been undertaken to explore the views and perspectives of selected stakeholder groups.

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 on the basis of input from all participants throughout the course of the day.

A **follow-up 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.

Delphi Conference

The first round of the Delphi Conference saw a draft Position Paper and a survey to guide responses to the Paper sent to 59 participants. 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

Society (ACS), Royal Australasian College of Pathologists (RCPA) Faculty of Science, Australian Pathology (AP), Public Pathology Australia (PPA)

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 in light of the replies of other members of their panel. It is hoped that during this process the range of the answers will decrease and the group will converge towards a consensus.

Responses to at least one "position" of the Paper (there were a total of nine positions) were received from 35 conference participants. The majority of respondents have a scientific professional association relationship while others identify 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.

The level of consensus achieved in Round 2 of the Delphi Conference was quite high (see Figure 2). 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%.

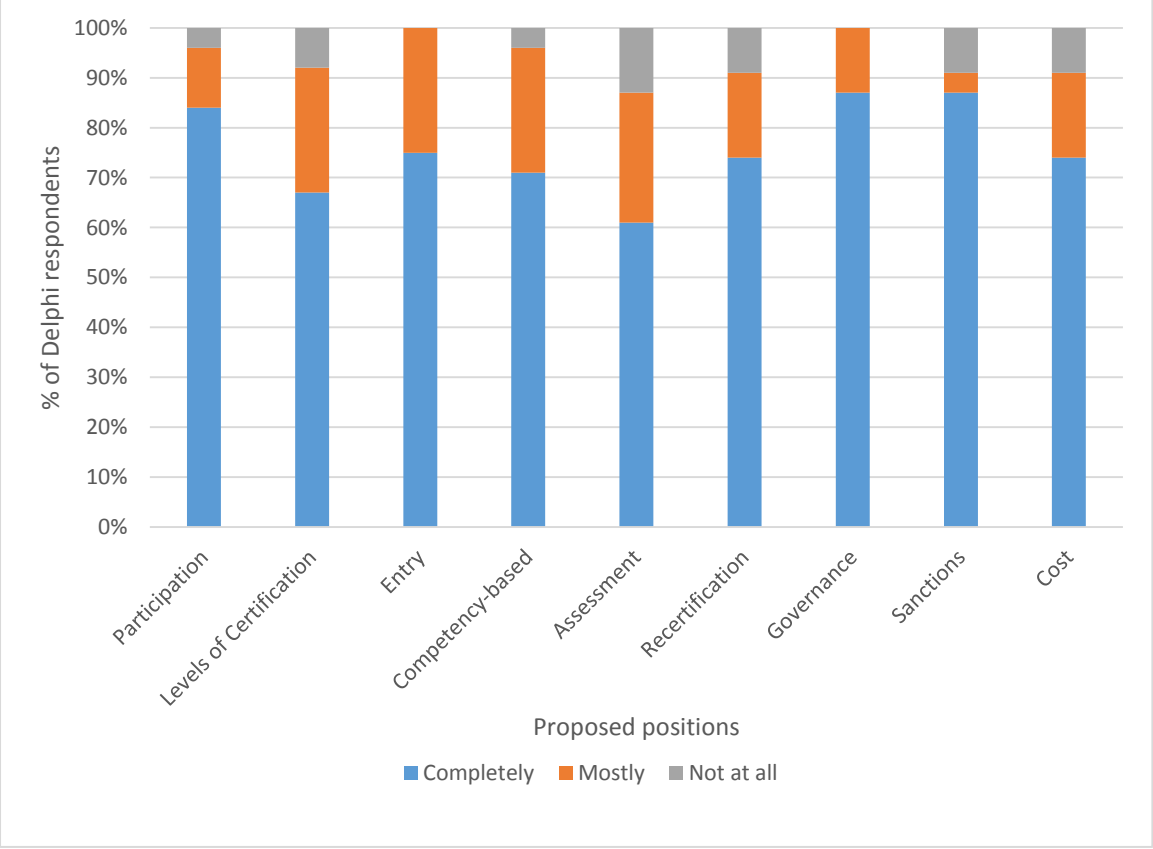

Figure 2: Level of consensus achieved in the Delphi Conference by proposed positions

The small proportion of respondents not agreeing at all with positions was quite low - between 5 and 10% - and their held positions suggested consensus would not progress further with more Delphi rounds. Accordingly, the Delphi Conference process was concluded after two rounds.

B. Defining certification

Prior to designing and establishing a system of certification, a common and agreed definition of the term 'certification' is firstly required. The term "certification" can be confused (and is frequently used interchangeably) with terms such as accreditation, licensing and registration. However, for clarity of discussion, they need to be seen as distinct systems or methods for ensuring quality standards in the delivery of services and products.

The United States National Council of State Boards of Nursing (NCSBN) provides a succinct definition of each of these systems as part of the Advanced Practice Registered Nurses (APRN) regulation processes (NCSBN, 2008):

- licensure (or regulation as it would be understood in Australia for health professions) is the granting of authority to practice to individual nurses
- accreditation is the formal review and approval by a recognised agency of educational degree programs in nursing or nursing-related programs
- certification is the formal recognition of the knowledge, skills, and experience of an individual demonstrated by the achievement of standards identified by the profession.

An important distinction of certification or licensing [registration] is that they are portable credentials that belong to and move with an individual (Knapp, 2000).

A more detailed definition of certification, as cited by Knapp (2000) from the US Department of Health, Education, is as follows:

> *"A voluntary process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Such qualifications may include graduation from an accredited or approved training program, acceptable performance on a qualifying examination, and/or completion of some specified amount or type of work experience."*

Another definition provided by the Principals Australia Institute is:

> *"The formal procedure by which the performance achievement of school leaders is assessed, verified and recognised in writing by issuing a certificate as to the attributes, characteristics, quality, qualification, or status of individuals in accordance with profession-developed requirements and the national standard" (*Ingvarson, 2014).

More relevant to the medical laboratory science workforce is the health-oriented definition offered by Gourley et al. (1997) from the US Board of Pharmaceutical Specialties:

> *"A voluntary process by which a practitioner's training, experience and knowledge are identified as meeting or surpassing a defined standard beyond that required for licensure. The purpose of certification is to protect the public's health and to advance the provision of pharmaceutical care."*

Perlstein (2014) similarly provides a health-oriented definition from the American Board of Nursing Specialties:

> *"The formal recognition of the specialized knowledge, skills, and experience demonstrated by the achievement of standards identified by a nursing specialty to promote optimal health outcomes."*

A recurring theme from these definitions is that certification is the formal and public recognition of ***an individual's*** experience, knowledge and qualifications according to predetermined standards.

C. Typical elements of professional certification models

Founding principles

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 of 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

A number of 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:

a. **Participation requirements** – is the scheme participation voluntary on the part of workers or made mandatory by government intervention (e.g. legislation) or employer requirements?
b. **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)?
c. **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?
d. **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?
e. **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?
f. **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?
g. **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?
h. **Sanctions** – what are the penalties and processes for non-compliance of the certification system as well as appeals processes and conditions?
i. **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)?

1. Participation requirement

Discussion

Background

Certification systems, unlike registration, are overwhelmingly voluntary in nature (Chanduvi, 2011; Gourley et al., 1997; Ingvarson, 2014; Knapp, 2000) and there is no requirement for certification to be undertaken.

Generally certification is seen as a complementary activity to the professional development of participants and the requirements of their current role - a 'value-add' to the employability of an individual (Chanduvi et al., 2011). It has been acknowledged that certification, even when ostensibly voluntary, can become more like a requirement or the default position if the perceived value for the individual, employing organisation or general public (Ayres, 2009; Culley et al., 2013; Perlstein et al., 2014) is sufficiently high.

Stakeholder sentiment

A majority of stakeholders throughout all the consultation processes thought the certification scheme should be compulsory at least at some point in its implementation. A minority of stakeholders, but a still significant number, felt certification should remain a voluntary scheme. A range of reasons were offered for each position. On the compulsory side, some argued from the logic perspective (e.g. if it is needed, it should cover the whole workforce) and others from a practical perspective (e.g. the numbers were needed to make the scheme viable). On the voluntary side, advocates argued that the scheme should offer sufficient benefit to attract a viable number of scheme candidates.

Despite strong support for compulsory certification, stakeholders conceded that, in practice, individual participation will likely need to at least commence on a voluntary basis. The recent draft final report of the Accreditation Systems Review (COAG, 2017), which considered a range of issues in relation to assuring the quality of health professional service in Australia, confirmed the likelihood that additional health professions would not be included 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.

Proposed position

In terms of government policy, therefore, a medical science workforce certification scheme would need to be implemented (at least initially) on the basis of 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 in order to make it viable. The key attractions for participation in the proposed scheme have been identified as:

<u>For workers</u>

- 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

<u>For professional associations</u>

- 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

<u>For regulatory authorities</u>

- 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)[2] 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 of 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.

[2] https://www.fertilitysociety.com.au/wp-content/uploads/2017-RTAC-ANZ-COP-FINAL-1.pdf

It is anticipated that this will be an incremental process, with a minimum three year period between initial entry to the scheme and recertification for individuals to prepare for the recertification process. For those applicants already working in Scientist or Technical Officer roles (and therefore deemed at least minimally competent and qualified to undertake those roles by their employer) at the time of scheme commencement, initial entry to the scheme will be granted in the form of a "grandfathering" certification arrangement. More rigorous assessment of competency, CPD and qualifications would be conducted (on a random audit basis) in the recertification process for this group. It is anticipated that competency assessment methods and recognition of skill processes would also continue to develop over time to support the benefit of this assessment process for scheme participants and employers.

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.

2. Levels of certification

Discussion

Certification systems may include levels of certification that address both horizontal (distinguishing between certified categories at an equivalent level of competence) and vertical (distinguishing between certified categories at different levels of competence) distinctions.

Vertical levels of certification frequently are in reference to related occupational hierarchies or functions (ASRN, 2015; Mackinnon et al., 2012). For instance, South Africa a medical science registration scheme covers the following comprehensive list of 'vertical' levels of possible registration:

- Clinical Biochemist
- Medical Biological Scientist
- Medical Physicist
- Medical Laboratory Scientist
- Intern Medical Laboratory Scientist
- Student Medical Laboratory Scientist
- Medical Technologists
- Intern Medical Technologists
- Student Medical Technologists
- Medical Technicians
- Student Medical Technicians
- Supplementary Medical Technicians
- Laboratory Assistants
- Student Laboratory Assistants
- Supplementary Laboratory Assistants.

By contrast, the New Zealand medical science registration arrangements encompass only three 'vertical 'levels:

- Medical Laboratory Scientist
- Medical Laboratory Technician
- Medical Laboratory Pre-Analytical Technician.

Horizontal levels of certification are also possible, wherein certification often relates to professionals who are at the same broad level of competence but may acquire competence in a more specialised skill set that is required in discrete workplace contexts. For instance, within the broad medical scientist profession, separate certification arrangements could pertain for cytologists, microbiologists, haematologist, etc. In the UK setting, these horizontal levels of recognition are identified, assessed and approved with the effect of acknowledging that the standards associated with an identified Scope of Practice have been met in addition to the broader standards of proficiency that must be met by all participants, no matter their specific scope of practice.

During consultations, there was initial strong support for both vertical and horizontal forms of certification within any proposed scheme for the medical science workforce. A survey of workshop participants during early consultations revealed most agreement (at least for the initial start-up stages of a certification scheme, see Figure 3) on the inclusion of vertical levels of scientists, especially entry-level scientists (67%), medical

scientists (76%) and clinical scientists (67%). For a more mature certification scheme, workshop respondents were willing to include senior scientists (62%) and technical officer (57%) levels. Ultimately, workshop participants and other stakeholders supported (somewhat equivocally) inclusion in a certification scheme of lower levels of the medical laboratory workforce such as laboratory assistants (47.6%).

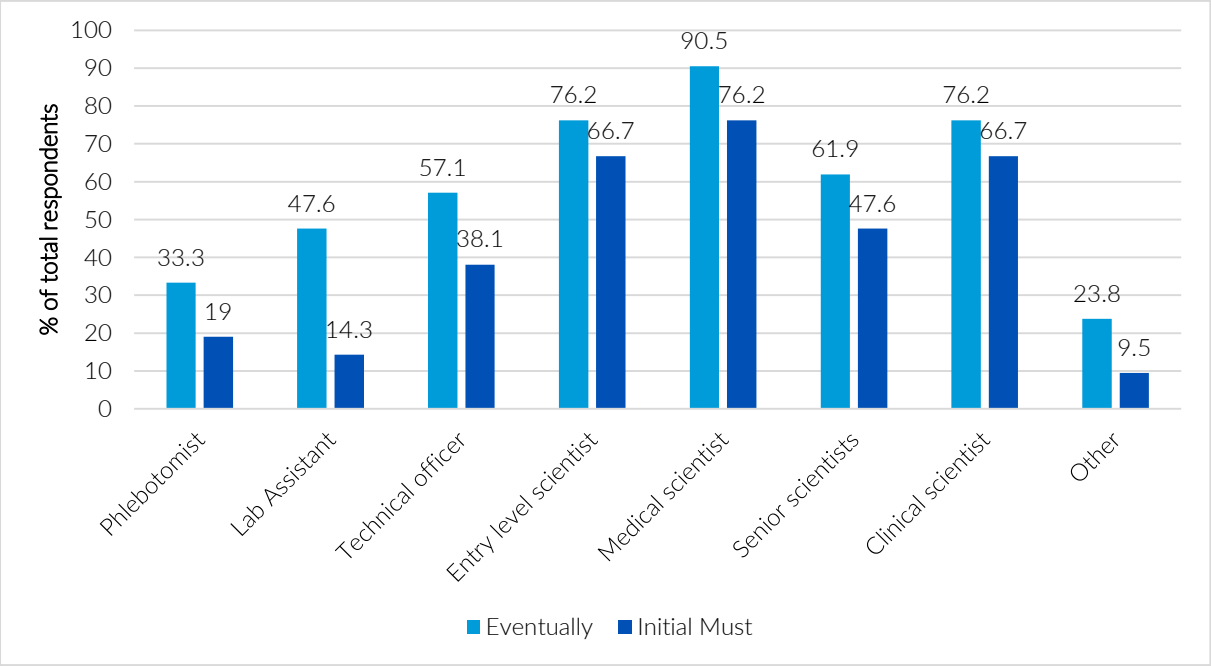

Figure 3: Survey respondent choices of suitable 'vertical' levels for certification (n=21)

Strong support for several vertical levels of certification was maintained through successive stakeholder consultation processes but concerns eventually began to arise about scheme complexity. In the final round of the Delphi Conference participants were evenly split with almost equal numbers suggesting there were too many vertical levels being proposed or that the number of vertical levels proposed was right. For those that argued there were too many levels - most concern fell on the inclusion of laboratory assistants and phlebotomists, for reasons ranging from the structural support those workforce groups might require (for instance in developing and maintaining competencies) through to the capacity of workers from these categories to bear the costs of certification. By that stage of the consultations, support had mostly consolidated to include only the levels of scientists and technical officers

Stakeholders offered strong support for a form of 'conditional' certification to new graduates until they could accumulate sufficient experience on the job to be properly assessed for their competence. Support for certification of laboratory managers was limited.

In regard to 'horizontal' levels, a survey of the Workshop participants during initial consultations found at least three-quarters of all respondents (n=21) identified nine separate discipline-specific areas for potential inclusion in a certification scheme (see Figure 4 below).

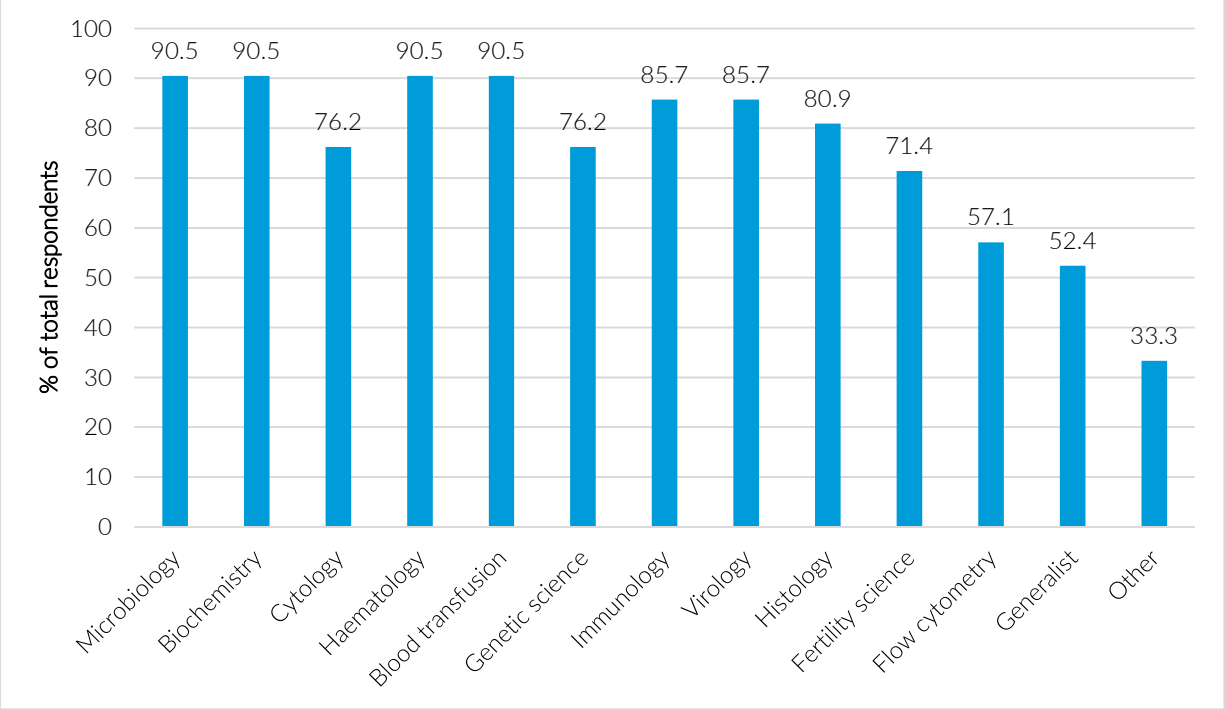

Figure 4: Survey respondent choices of suitable 'horizontal' levels for certification (n=21)

As with the vertical levels of certification, as the consultations widened concerns were increasingly expressed about the potential complexity of the scheme with so many levels to implement, and sustainability concerns about so many specialist areas needing to be maintained (for instance regular reviews of competencies). Some respondents questioned the need for 'specialist' categories at all, arguing that at the scientist level, the skills set required to be certified should be more generic in nature and appropriate to all areas of medical science.

Most of the respondents who felt there were too many horizontal levels accepted that the seven RCPA categories of 'specialisation' were appropriate. Others though argued that the RCPA categories, while suitable for pathologists, did not represent always the way scientists specialised and also excluded non-pathology classes of medical science workforce. An interesting argument was also mounted by a few to not unnecessarily lock in the horizontal certification categories, given the rapid pace at which medical science was evolving. Stated one respondent in regard to the RCPA categories:

> *"This would unduly restrict the scheme, limiting entries to 'the more traditional' disciplines. So long as each discipline is prepared to do the work to define the vertical levels or specific criteria required for competency then different medical scientist disciplines should be included. This will enable the scheme to develop over the next 10 years to encompass new and developing disciplines and ensure it is forward-thinking."*

The above quote reinforces the proposal that a determining factor for inclusion should be the willingness of an area of specialisation (its representative association) to do the work required, over a sustainable period of time, to support the certification scheme.

Proposed position

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:

a) lower levels of the medical science career path had potentially the most motivation for certification, and
b) the less highly qualified and skilled laboratory workforce component is that 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 1 below. The proposed certification levels in this table are linked to levels of the Australian Qualification Framework (AQF)[3] 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 (see **Appendix B**for further detail).

Table 1: 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

[3] https://www.aqf.edu.au/

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

A. **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[4].

   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.

B. **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 skills 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 in order 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).

C. 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 of the specialist areas included in Figure 4 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

[4] 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.

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 Masters degree. 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, in order 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.

D. **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 level 10[5] or equivalent doctoral level degree, in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising.

In Table 1 above, the possible vertical levels of Laboratory Assistant and Phlebotomist/Specimen Collector are not included in the list at the moment but may be included at a later date. A number of 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.

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 in order to ensure that all contexts have been addressed.

[5] https://www.aqf.edu.au/aqf-second-edition-january-2013

3. Entry requirements

Discussion

Most certification schemes place boundaries or hurdles to accessing or seeking to access certification. Certification entry requirements typically include:

- sufficient or entry-level educational experiences (Alpha Scientists in Reproductive Medicine [ASRM], 2015; Gourley et al., 1997; Mackinnon et al., 2012; Termuhlen, et al., 2016)
- completed training with an accredited or approved training program (Mackinnon et al., 2012; Termuhlen et al., 2016)
- a defined or minimum time of practical experience (Ingvarson, 2014)
- currently practising in their profession (Ingvarson, 2014).

Entry requirements need to be carefully considered and selected according to the needs of the profession. More importantly, entry requirements must be defensible, fair and reasonable so as not to possibly (and inadvertently) exclude qualified candidates (Knapp, 2000).

Scientists

Initial entry

Entry to the role of scientist in medical laboratories is widely accepted as requiring a relevant degree in Medical Laboratory Science, Science or Applied Science (AQF Level 7 or 8 qualification or above). Although a number of university degrees are accredited by AIMS as suitable for supporting medical laboratory science practice, successful entry to the scientist workforce widely occurs on the basis of a range of other science degrees that are apparently deemed acceptable and suitable by laboratory employers.

There has been no compelling evidence found to suggest that a certification scheme should impose a higher standard for initial entry and, apart from a group of respondents who are strongly supportive of the AIMS-accredited degrees in medical laboratory science, stakeholder consultations have widely supported this broad-based position.

The new scheme would, however, introduce a mechanism for documenting the range of degrees considered suitable by employers to support adequate professional practice in their laboratory workforce. Under the proposed scheme, a working group of the Scheme governance arrangement would develop an initial list of acceptable individual qualifications (in addition to those already accredited by AIMS) that would confer automatic initial entry. How the working group developed that list (nominations from shareholder professional associations, survey of employers) would be up to the working group but that process could be informed by the process and criteria that AIMS currently uses for overseas qualification assessments.

Since some potentially suitable qualifications might be inadvertently left out of this list, other qualifications sought to be recognised by certification candidates would be checked via desktop review of the transcript by the certification governing body, initially on a case by case basis until an exhaustive listing of all available suitable qualifications has been established. New qualifications that appeared in the future can be added to an updated list over time as required.

Length of entry period and possible early certification entry

The case study work indicated that a 'limbo' period of more closely supervised practice between completion of qualification, entry to the profession and full professional certification occurs quite commonly in other professions and jurisdictions in the form of provisional / associate / conditional certification or registration status. There are many models that indicate the utility of this staged approach to full professional recognition, with a range of different 'hurdles' being applied in the various models – from simple time spent in the workplace to documentation of practice and/or competency achievement to formal examination processes.

In the workshop discussions and Delphi conferencing process, there has been widespread agreement that certification should occur at a point that is later than initial entry to the workforce and after initial qualification for commencement as a scientist. However, respondents noted that the initial competencies of entry-level scientists should be given due recognition in the certification framework and respect in the workplace so as not to create an actual or perceived barrier to workforce entry or employer recognition of entry-level competence to perform scientific duties.

The current NPAAC definition of "scientist" has for many years included a requirement of 2 years' professional practice in an accredited laboratory before that role definition can be applied. This aligns with the observations of a number of workshop participants and Delphi conference responses that there is already at least an informal acceptance of the need for a staged process of involvement and delegation of responsibility to entry-level scientists in the work of laboratories.

The concept of a pre-certification period is also reflected in the current requirements for and complexity of certain types of discipline-specific practice. For example, as noted above, current recognition as a cytologist requires two years of post-graduation workplace practice in addition to successfully completing the Cytotechnologist examination process. Genetic scientists also reported that, although there is not a formal requirement currently associated with it, the majority of new entrants to that field would more than likely require in excess of two years supported practice in the workplace before they could confidently and reliably undertake fully independent professional practice in that field. A period of two years' practice prior to full certification therefore appears to sit quite consistently with existing arrangements and definitions.

Automatic certification on the basis of membership of a professional association was not widely supported during consultations. Respondents were wary of the variability of membership requirements and the associated challenges for ensuring consistency between disciplines / organisations and called for careful consideration of this issue.

In the final Delphi conferencing round, 83% of respondents agreed that 2 years of workplace practice post-entry would be a suitable stage at which full or unconditional certification would be appropriate if all requirements were met.

Technical officers

Initial entry

Access to certification by technical officers is slightly more complex due to the current workforce makeup. In addition to technical officers who hold an appropriate VET qualification (for which they would have been required to undertake significant workplace practice to obtain as well as meet other formal assessment requirements), there is a reportedly high number of workers with science degrees who currently hold

technical officer jobs. This workforce situation has been confirmed by scientists, employers and union representatives.

This variation of initial qualification creates some potential (but not insurmountable) complexity with regard to the assessment for entry to the technical officer role. Similar to the situation for scientists noted above, a working group of the governance structure can construct a list of suitable qualifications at the AQF 5 / 6 level that would be acceptable to education institutions and employers for initial certification. Acceptable VET qualifications would be competency-based and should correlate with the medical scientist competency framework / scope of practice document. Individuals with a relevant science degree but applying for technical officer certification would be considered to have met minimum entry requirements for this level[6]. As per the similar situation for scientist entry, judgements might need to be made as to how well each degree correlates and satisfies the competency requirements of the competency framework / technical officer level scope of practice.

Length of entry period and possible early certification entry

Stakeholders who participated in the Delphi Conference were strongly supportive of the application of a two-year entry period prior to certification for Technical Officers, in line with that recommended for scientists.

Other workforce groupings

In line with the views of the majority of stakeholders, the existing workforce grouping of Clinical Scientists (as per the NPAAC definition) and proposed workforce grouping of Specialist Medical Scientist are not proposed for inclusion in the initial certification implementation phase. Further work is proposed on the part of the certification body and participating stakeholders to explore appropriate mechanisms for defining the relevant competencies in more detail and, subsequently, relevant arrangements for monitoring the maintenance of competence.

Reduction of waiting period

Regarding the issue of previous experience gained in a laboratory via pre-graduation placements, only 50% of respondents were convinced that this experience could be considered as equivalent to formal employment, and therefore allow a reduction in the 'conditional' certification period. This hesitation was largely attributed to the variability of placement experience in terms of acquisition of skills and competence and the often distinct difference between undertaking practice in the role of a supervised student versus the more rigorous requirements of undertaking practice as a fully qualified but entry level scientist with substantive duties.

By contrast, there was strong support for some form of reduction in waiting time for technical officers with science degrees who had worked for a minimum of two years as a technical officer and were applying for certification at the scientist level.

Similarly, there was more support for graduates from VET courses getting a more fast-tracked process to full or unconditional certification on the basis that their training involved significant on-the-job experience more akin to an apprenticeship than the laboratory practice normally included in degree courses.

[6] Those with a science degree working in a technical officer role but seeking scientist level certification would be subject to the requirements of scientist certification.

Proposed position

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) 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 the course of 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 (which would need to be developed but might be similar to the UK document which is provided at **Appendix E**).

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.

4. Competency-based certification

Discussion

Support for a competency-based approach

Certification systems generally require the development of standards to measure competence (Knapp, 2000). A competency standards framework can include a combination of technical and professional skills (Chanduvi et al., 2011) as well as non-technical skills that might include critical cognitive skills and interpersonal abilities, such as skills in communication and collaboration, that complement technical skills (Wang et al., 2011). The majority of Delphi Conference respondents (71% completely and another 25% mostly) supported the use of a competence based certification scheme.

A competency framework provides a model of the desired outcome by defining required competencies as well as how they should be assessed (ASRM, 2015). Direction on assessment is seen as a necessary tool for certification programs (Wang et al., 2011). Several stakeholders consulted for this project were keen for a competency framework for the medical scientist workforce to include values and attitudes, especially in regard to pride in professional performance and completing work to the highest quality. For instance one stakeholder offered the opinion:

> *"Professional competence = Initiative + knowledge (professional contribution above and beyond basic training)"*

Development of competency frameworks is in some cases undertaken by the certifying body (e.g. National Accreditation Association for Translators, 2016), or by other regulatory agencies, training institutes or working groups from the profession (e.g. ASRM, 2015; Sonstein et al., 2014).

The existing competency framework

A competency based standards (CBS) framework which sets out competency standards for several parts of the medical scientist workforce (laboratory assistants, technicians, scientists, senior scientists) has been in existence in Australia for over a decade (Pathology Associations Council [PAC], 2009) and has been reviewed several times. The framework details 10 broad areas or domains of competence, and within each area a scope of practice identifies the minimum competence requirements for each part of the medical scientist workforce. By design, it is a 'nested' competency framework, meaning that lower level competencies must be mastered before higher level competencies can be addressed. Some Workshop participants raised concerns with this design, particularly as it might promote a possible need for scientists to have to demonstrate proficiency in lower level competencies, but this is not generally how nested competency frameworks operate in practice.

Workshop participants were evenly split on whether they thought the current Pathology Associations Council-approved CBS framework for medical scientists is adequate to support a certification scheme without change (48%) or with some improvements (52%). No-one thought them entirely inadequate. Participants also discussed the usefulness of the current Scope of Practice document and agreed that, although there was quite a bit of useful differentiation between the various levels of roles and responsibilities in the laboratory and pre-analytical workforce, further work would be helpful in order to clearly distinguish the relevant competencies associated with the different levels.

At a recent meeting of PAC in August 2018 specifically convened to discuss the CBS framework, the framework was tested for three scientific workforce positions … a clinical scientist, a genetic scientist, and a basic level biochemistry scientist. The existing list of competencies proved almost entirely adequate for all three roles, with additional requirements suggested for only a few competencies.

The most common concern with the existing CBS framework identified by both Workshop and Delphi Conference participants is the way the CBS framework deals with discipline-specific competencies. Just over half (57%) of the Delphi Conference participants felt the framework needed to satisfy better the specialist areas of practice. One Delphi Conference participant noted:

> *"The competency framework is too generic. There needs to be discipline specific competencies built in to cover for competency in [for example] cytology screening, blood banking antibody investigation, cross-matching, haematology blood film morphology, etc. Competencies relevant to their professional role."*

Building on the current competency framework

A number of suggestions for improvement of the current PAC CBS framework were provided from the stakeholders through the different consultation processes and included:

> *"… requires reference to guidelines and examples of acceptable documents so candidates know what standard to work towards."*
>
> *"It would good to have some finer distinction between what is required by Technical officers, Scientist and Senior scientists (Clinical Scientists)."*
>
> *"Some of the definitions need to be updated and the competency frameworks and scopes of practice reviewed against current 'best practice' and developments in technology."*
>
> *"A number of sections have clauses which are too vague or potentially subjective to facilitate uniform application e.g. professional development section."*

Stakeholders noted the wording of the current CBS framework is not always fully inclusive. For instance, not all wording is fully relevant to the work of embryologists (e.g. terminology of specimen versus sample or a combination of both, testing as opposed to procedures or a combination of both).

The recent PAC meeting noted that, despite widespread acceptance of the CBS framework, its widespread referencing in university courses, and repeated confirmation of its validity through successive reviews, it remains poorly utilised. This was thought to be partly due to a lack of widespread promotion, but also because:

a) its specific utility to underpin a range of human resource development and management functions has not been adequately clarified to employers and others, and
b) the means for using the framework to assess competence, including the provision of assessment tools, has not been supplied to those employers that might want to use the framework.

Proposed position

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 is required 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.

Such refinement has been largely agreed to be important and required, but not too considerable in nature.

Process for improving the competency framework

Since the PAC still 'owns' the CBS framework, they should be given the first opportunity to re-draft it in line with the requirements being expressed. As noted earlier, the PAC was convened recently and confirmed the current standards to be largely appropriate but needing some refinement (see above), along with the development of assessment tools and a means of promoting the framework for broader employer use. PAC will seek the resources to support this effort. PAC members, especially the discipline specific professional associations, will need to be consulted.

In attempting to cover the specialist area competencies, the CBS framework editors will need to be mindful that this could be done though writing new ('specialist') competencies or through constructing assessment tools flexible enough to assess a [generic] competency within specific workplace contexts. A combination of these approaches is also possible.

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 a majority of Delphi Conference participants.

The workshop participants that looked at this issue identified a number of potentially high risk public safety and quality competencies from the current Australian CBS framework. These are detailed in **Appendix C**. Although there was not necessarily strong support for a major focus on high risk competencies for the certification scheme – the majority of Delphi Conference respondents favoured the inclusion of higher risk issues within the context of broader professional competence factors – Delphi Conference participants considered this Appendix C list and have provided input, which is now summarised and included in the same (updated) appendix.

In the light of the Certification Project's discussions and in collaboration with the PAC (plus invited others, such as FSA, THANZ, and ASC), the current CBS framework will continue to be refined with a view to its adoption by the new scheme over the coming 12 months. After this initial review process, the framework will be subject to review by the certifying body and its participating stakeholders at regular intervals from that point on (timeframe for further review to be given further consideration during the coming review process).

5. Methods of competency assessment

Discussion

Certification schemes based on competence require more proof of current competence rather than evidence of relevant training and / or achievement of a particular qualification. This implies some form of (independent) assessment, which has been defined as (Australian Skills Quality Authority, 2015):

> *"… the process of collecting evidence and making judgements on whether competency has been achieved, to confirm that an individual can perform to the standard required in the workplace …"*

Assessment of competence is generally conducted through a single but more often a combination of methods for the attainment of initial certification and recertification. Competence assessment for initial certification can include the following methods:

- examination (Gourley et al., 1997; Mackinnon et al., 2012), including online examination (reference, Health Informatics Society of Australia [HISA])
- logbooks, for example a log of cases of techniques practised and utilised (ASRM, 2015; Culley et al., 2013)
- oral assessment or interview (Chanduvi et al., 2011)
- self-assessment against a competency checklist (Chanduvi et al., 2011)
- portfolio[7] that demonstrates evidence against performance standards or competencies (Ingvarson, 2017)
- Supervisor's report[8].

The merits of each of these methods and the relative cost and associated risks (of not accurately assessing competence) were detailed in the Discussion Paper (Stanford, et al., 2017).

Most certification schemes employ more than one form of competency assessment. The existing schemes in Australia reviewed found assessment methods vary significantly in nature and depth of the scrutiny of competence, ranging from comparatively low cost online examinations and online learning modules to very intensive interview and written examination processes. All but one scheme had more than one assessment method. Most certification schemes include an assessment of on-the-job experience / performance.

Selection of assessment methods

A survey of workshop participants found strong support for only a few assessment methods including portfolio evidence (76%), examination (48%), supervisor assessment (44%) and logbook (40%), as shown in Figure 5.

[7] Workshop participants noted a portfolio could include case reports, research publications, and reviews of published research articles.

[8] The workshop participants also noted a 'referee report' from an expert who knows the skills and knowledge of the worker being assessed.

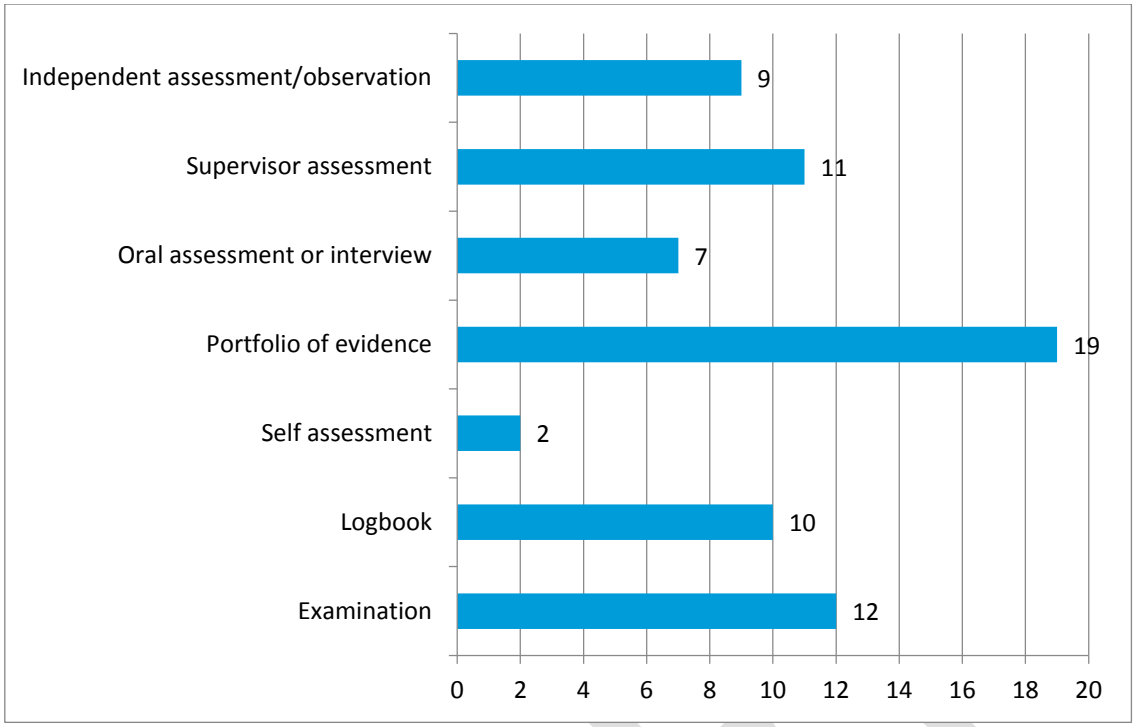

Figure 5: Preferred assessment methods of workshop participants (n=25)

In the proposed position for the 1st Round Delphi Conference, the following assessment methods were recommended:

- self assessment
- examination (online)
- portfolio of evidence
- maintaining a log book

Most respondents in each Delphi round (61% and 60%) fully accepted the proposed array of methods and considered the balance had been found between credibility and cost, while another 30% and 27% mostly accepted the proposed methods with some caveats. Those who did not completely agree believed that the number of methods could be onerous for certification candidates, the examination might be superfluous, and that 'self-assessment' might lack credibility. The following quotes from Delphi Round 2 participants indicates that this component of the certification framework scheme is understandably likely to be one that needs special attention and refinement:

> *"Examination may not be applicable in all circumstances; portfolios show the work and study undertaken; log book will allow assessment of continuing education at an effective level; self assessment draws the applicants attention to the requirements that are not just routine duties or multi tasking."*

> *"The proposed model is too onerous and potentially places a large burden on both candidates and employers. An online examination and a simple logbook is sufficient. The logbook should consist of only a checklist of skills to be ticked off by a supervisor. There is no need for a portfolio, which creates an unreasonable barrier to certification and will be a large impost on employers in terms of the time a candidate spends and the resources of employers."*

> *"Examinations, case studies, log book? Surely these type of assessment would be used for completion of a higher qualification, not just competency, unless everyone who becomes competent gets a fellowship? Are you expecting technicians to have to sit exams?"*
>
> *"The portfolio of evidence and some form of independent assessment is important. Examination would give an indication of the currency of the knowledge of the candidate.*

As these responses confirm, choosing between methods of assessment is not as easy as simply selecting the approach or approaches that will deliver the best form of evidence of competence. Selecting assessment methods is invariably a balancing act between desired levels of credibility (that is to optimise the worth of the evidence of competence) and acceptable levels of cost, scheme practicality and potential participant accessibility.

The content requirements for all recommended or required forms of assessment would need to be quite clearly specified for the different levels of certification and would include prompts for assessment of technical skills as well as involvement in quality assurance/improvement activities and other professional development activities. The assessment methods, including tools to support assessors, could also be developed in conjunction with the ongoing development of the CBS framework, potentially even using the same processes.

An example of one type of tool that has been used for some years now for recording competency development and assessment against the current CBS framework in a biochemical genetics laboratory setting in the NSW public sector is provided at **Appendix D**.

Links between competency assessment and current and future CPD programs

A number of respondents also noted a significant opportunity for recognition of existing and future (emerging) CPD activities, subject to an assessment by the certification governing body of the value of specific activities in promoting development and maintenance of professional competence as appropriate for each certification level. As noted in this project's Discussion Paper (Stanford et. al., 2017), that opportunity would be in keeping with the direction of peer professions as all other Australian health professions (both formally regulated and self-regulated/certified) which is they are also moving toward an alignment of CPD activities with their professional competency frameworks. An outline of an example CPD scheme is provided below on page 41 in the section on recertification.

Assessment process

Delphi Conference respondents strongly supported (74%) involvement of an independent reviewer whose role would be primarily to review and verify the evidence provided to support clients' applications for certification. This independent review process was seen as a key component of the proposed scheme's credibility. The minority who equivocated on this issue did so largely on the basis of assumed (unsustainable) costs. Costs, though, could be reduced if reviewers could be deployed on a voluntary basis, which 48% thought possible, especially if reviewers could be rewarded with CPD points and/or progress with their own re-certification process through inclusion of that activity as part of their own portfolio of evidence. In addition to the 48%, a further 30% thought that a mixture of volunteer and paid reviewers might be possible (as per the laboratory accreditation assessment arrangements), while 17% believed only paid reviewers were viable.

Subject to sufficient funding being available to the scheme to support this strategy, the proposed position would be to have a mixture of (uniformly trained) volunteer and paid reviewers undertaking the assessment

of portfolio evidence, and potentially verifying the evidence through observation of performance, for worker certification. Onsite review would, of course, be an expensive assessment component and may need to be considered for delayed introduction once the scheme's income base had been well established. Sample audits are a common feature of certification assessment schemes, relying on the possibility of being audited for applicants to properly meet the scheme requirements and providing a cost effective mechanism for the assessment process. The majority (91%) of Delphi Conference respondents indicated that they would accept a sampling rate of between 5% and 10% of all assessments as being appropriate.

Accordingly, it would be possible to allow the governing body of the scheme to make a determination on the assessment methods, if finances and profession-based support allowed them to use independent reviewers for all competence assessment. If this was not financially sustainable, then the bottom line would be to use workplace supervisors but audit at least 5% of competency assessments and take appropriate actions against supervisors who regularly assess competence in a questionable manner.

There was also strong agreement from Delphi Conference respondents that assessment guidelines and tools should be developed to minimise the variation between assessors as much as possible. These guidelines would seek to ensure uniformity of assessment across all the specialist discipline areas. Again, this is a challenge that that is shared with the accreditation assessment process.

Stakeholders have repeatedly drawn attention to the existence of competency assessment as a requirement in the current accreditation framework (as noted earlier in this paper) and pointed to potential opportunities for the certification scheme to align its requirements to that process. This will require more detailed consideration over time, especially given that there appears to widespread agreement that this element of the accreditation assessment requires further development.

But, given that both processes will look to the one national competency framework for the scientific workforce in pathology laboratories, it is worth noting the relevant requirements, as follows:

> **Section 5.1.6** of **the ISO 15189 Standard,** as referenced in the NPAAC Requirements for Medical Pathology Services, 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.
>
> NOTE 1: Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:
>
> a) direct observation of routine work processes and procedures, including all applicable safety practices;
> b) direct observation of equipment maintenance and function checks;
> c) monitoring the recording and reporting of examination results;
> d) review of work records;
> e) assessment of problem solving skills;
> f) examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.
>
> NOTE 2: Competency assessment for professional judgment should be designed as specific and fit for purpose.

Proposed position

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 has been developed for consideration:

A. 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[9]

B. Portfolio of evidence of professional development, which would include –

1. 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[10]. 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.
2. **Evidence of other professional development activities** undertaken during the conditional practice period[11].

The assessment process will be arranged by the certifying body, preferably using a mix of paid and volunteer assessors, depending on the availability of funds in the scheme. In the short term, it is anticipated that most assessment will be done via desktop review and according to a selective audit process (detailed review of between 5 and 10% of applications per workforce group per annum).

For fairness purposes and the overall credibility of the scheme, significant efforts will need to be made by the certifying body to ensure that its assessment regime is conducted consistently and fairly. In addition, the potential to align the certification arrangements with competency assessment of individual workers as part

[9] 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.

[10] 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.

[11] 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.

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.

It is clear that further work is required in order 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 in order 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.

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.

6. Recertification and maintenance of certification

Discussion

Importance of recertification

Recertification or maintenance of certification is a feature of most certification systems. Recertification may be required annually to every three years (Chung et al., 2011; Mackinnon et al., 2012; Termuhlen et al., 2016) with some agencies requiring additional assessments such as cognitive exams to be undertaken every 10 years (Chung et al., 2011; Termuhlen et al., 2016).

Recertification is seen as a mechanism for demonstrating a commitment to continuous improvement and, in the case of healthcare, is a statement that quality patient care is a priority for practitioners (Chung et al., 2011). It is also a useful mechanism to bridge the information gap between the consumer and provider where maintenance of certification 'sells confidence' through branding that offers high standards and piece of mind to the consumer (Jha, 2015).

Common methods of assessment for recertification can include:

- examinations ranging from every five years (Gourley et al., 1997) to every 10 years (Termuhlen et al., 2016), written or oral (Wang et al., 2011)
- simulation education (Culley et al., 2013)
- submission of evidence of CPD, for example Continuing Medical Education (CME) points (Ayres et al., 2009; Termuhlen et al., 2016).

Recertification and maintenance of certification is not without limitations or detractors, largely related to dissatisfaction with the methodology and process of recertification or that recertification simply measures compliance and possibly encourages mediocrity (Jha, 2015; Knapp, 2000). Processes for recertification therefore need to be carefully considered and designed to enure that the process is less onerous and complex than the initial entry process.

In line with these viewpoints, stakeholders agreed that recertification needed to consider the quality of an individual's day to day practice in the workplace primarily through a combination of evidence of relevant CPD activities and assessments of competence.

Discussions at the workshops also highlighted that accesible pathways for re-entry to practice needs to be considered as part of the recertification process. This would ensure equitable recognition for workers who may have taken time out of the profession for various reasons such as caring responsibilities or illness.

Duration

Recertification, as with the initial certification process, requires an assessment of competence in the context of experience, speciality and workplace environments. In contrast with initial entry, however, stakeholders agreed that it would be appropriate for the recertification process to be simple, affordable and accessible in terms of cost, the time and resources required and re-entry into the profession (e.g. part-time workers, workers on carers leave) to encourage participation by workers and employers. Additionally, the process of recertification would need to maintain rigour to adequately assess quality and competence.

A range of options for suitable recertification periods between 3 and 5 years were considered by workshop and Delphi Conference participants but 3 years emerged as the preferred and recommended option.

Points-based systems for recertification

In a points system, each type of evidence of maintained competence is assigned a value or points and the points are accrued over a period of time. This system is adopted by various CPD programs such as the American Society for Clinical Pathology's 'Credential Maintenance Program' (CMP).

The recertification system, or CMP, as described in the *US Credential Maintenance Program Booklet*[12], requires individuals to obtain between 9 and 45 CMP points (1 CMP point = 1 hour) every three years to retain credentialing. Evidence is submitted online and individuals are required to retain copies of their evidence in the event of an audit.

The type of activities is defined for each certification category ensuring a cross-section of relevant activities. For example, Medical Laboratory Scientists are required to accrue a total of 36 points as follows:

- 1 point in laboratory or patient safety (i.e., QC, quality assurance)
- 2 points in each of the following: blood banking, chemistry, haematology, microbiology
- Remaining points in area(s) of lab specialty, immunology, molecular diagnostics, management, education, or other related laboratory areas of interest.

Similarly, NZ Institute of Medical Laboratory Scientists (NZIMLS) CPD program is based on a points system linked to laboratory competencies and continuing education in the Medical Laboratory Scientists (MLS) profession. Individuals are required to accumulate 100 points per year or 300 over a three year period[13].

The points based system utilised by the Royal Australian College of General Practitioners' (RACGP) Quality Improvement and Continuing Professional Development (QI & CPD) Program requires individuals to accrue a minimum of 130 CPD points over a three-year period. This must include:[14]

- one planned learning and need (PLAN) QI activity
- one Category 1 activity
- a cardiopulmonary resuscitation (CPR) course.

Absence from the workforce

Discussions at the workshop also highlighted that accessible pathways for re-entry to practice needs to be considered as part of the recertification process. This would ensure equitable recognition for workers who may have taken time out of the profession for various reasons such as caring responsibilities or illness.

[12] American Society for Clinical Pathology (2018). U.S. 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-international-booklet-final-web.pdf?sfvrsn=8

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

[14] The Royal Australian College of General Practitioners. *QI&CPD Program: 2017–19 triennium handbook for general practitioners*. East Melbourne, Vic: RACGP, 2016.

Proposed position

Duration

The proposed position is a certification frequency cycle of 3 years.

System of recertification

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 in order to accumulate sufficient 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 sufficient 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 2 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 2: 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.[15] 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 of time 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 course of 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 assesses competency. 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 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. For those who continue to choose not to join a professional association, the certification scheme may offer alternative CPD-relevant content that would support its progress toward a more competency-focussed certification arrangement.

[15] 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,

7. Accountability and governance

Discussion

Fiscal and administrative independence from related professional and educational bodies is seen as vital for the credibility and accountability of any certification system (Knapp, 2000). During the development phase of a certification program, as described by Knapp (2000), a professional association may appoint a taskforce or planning group to determine the feasibility of a program and go on to create the by-laws, structure and implementation plan for the operation of a certification body and then separate from the professional association once established. Alternatively, the certification system may be launched independently from the beginning with seed funding.

Rules,by-laws and/or a constitution provide a road map of the organisation's purpose as well as how it will function and include details about overarching objectives, board structures, composition, appointment and terms of office. Board members of not-for-profit organisations[16] typically serve on a voluntary basis and membership composition may include relevant stakeholders from the profession as well as members external to the profession (Gourley et al., 1997).

In Australia, the two most common structures for the operation of not-for-profit organisations (and that give protection to board members from the financial and legal commitments of the organisation, apart from that associated with fraudulent behaviour) are a) an incorporated association, governed by a management committee, and b) a company limited by guarantee, governed by a board of directors. Members of each of these governing structures hold responsibilities for governance that are set out in relevant State/Territory and/or national regulatory arrangements.

As set out in guidance from the Australian Institute of Company Directors (AICD)[17] and elsewhere, in addition to clear and comprehensive rules for the organisation, the composition, roles and structure of a board is one of the most critical aspects of successful establishment of a new organisation. Board directors need the right balance of skills and experience to work collectively to provide guidance to employees, assess and manage risks, pay careful attention to the needs of stakeholders, and to meet their formal legal responsibilities for the financial affairs of the organisation.

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[16] It is assumed that the proposed certification body will be set up for the benefit of the profession and that any income will be directed back into activities that will provide benefit to applicant and certified members – i.e. a not-for-profit venture.

[17] https://www.ourcommunity.com.au/management/view_help_sheet.do?articleid=2104

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/05446-3-11-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

Not-for-profit organisations tend to have higher expectations placed on them for engagement with and responsiveness to their stakeholders. A common mechanism for ensuring close engagement with stakeholders is the establishment and operation of an advisory board. Although advisory board members do not hold the formal fiduciary responsibilities of governing board members, the organisation's rules can be set up to ensure that key information is regularly shared with the advisory board and their views on a range of issues are put forward to the board for inclusion in decision-making considerations.

For companies, there is the option of offering formal shareholding in the organisation to multiple parties, with legal and financial liability of shareholders limited only to the value of the unpaid calls (if any) on their shares in the company. An additional option is a company limited by shares that operate as "for profit" subsidiaries of the parent not-for-profit company (Our Community, 2018).

Consultations to date

Workshop discussions and the Delphi Conference have provided strong support (87%) for the proposal of an independent governance mechanism that is fair, transparent and accountable in its operation, including for assessment purposes. Stakeholders have agreed that the certification scheme's governance mechanism needs to be representative of stakeholders' requirements of a certification scheme and there was strong support for incorporation of relevant professional association representatives in the running of a certification body.

Board membership

The majority of participants strongly felt that a board made up of 7-12 members would be the most workable number and that some consideration would need to be given to how a core representative group could be defined without excluding willing participants (e.g. via the use of influential advisory groups for designing the content of the assessment framework).

The Delphi conference feedback did not generally favour a weighted approach to board membership based on association membership. However, support for the possibility of some form of rotational participation in the operation of the governing board, given that not all interested stakeholders and people with the necessary governing skills could all participate in an effective board with day to day operational responsibilities.

After some discussion about the pros and cons of including employer representatives on the board, workshop participants recommended that employer organisations should probably not participate in the governance of a certification scheme but acknowledged that they would be key stakeholders for input to initial and ongoing consultation on the operation of the scheme. This view was also supported by the Delphi Conference but respondents strongly acknowledged that it is very important to ensure that the certification arrangements integrate well into workplaces where professional practice is undertaken. It should be noted, though, that the private sector pathology employer association has expressed strong interest during consultations in participating in the governance structure due to its members' perceived need to have a voice in discussions and decision-making that could have a significant impact on employers.

The Delphi Conference considered a proposed Board of up to 12 members that would be made up of:

- an Independent Chair
- a representative with legal experience
- a representative with financial /accounting experience
- a consumer representative

- an NPAAC representative, and
- participation of between four to seven nominees from the professional associations that have become shareholders in the Accreditation (Certification) Body - on an agreed rotational basis, which may be assisted by an agreed approach to a broad grouping of scientific practice specialisation.

87% of Delphi Conference Round 2 participants supported this proposed position, which also included the proposed use of discipline advisory arrangements and the inclusion of relevant medical science professional groups from outside the pathology sector. Participants who expressed caveats on their support tended to query the need to keep board positions specifically open for people with legal and financial/accounting skills. AICD guidance recommends that boards ensure that they have good access to input from individuals with legal and financial management experience

The concept of some form of rotational participation in the board was supported, although the detail of how this rotation process might operate still requires further thought and elaboration. One possible tool for assistance in ordering a process of rotation is the application of the UK Health and Care Professions Council's sub-categorisation approach to biomedical scientist specialisation – that is, grouping specialisations under the broad headings of blood sciences, infection sciences or cellular sciences – was tested in the Delphi Conference Round 2. Although 65% of participants supported such an approach, many were unclear on the detail of how discipline interests fitted into those categorisations and were therefore not supportive, at least in the first instance.

Advice provided in the reference material included above from the AICD sets out in some detail the range of roles and responsibilities that board directors operating in successfully governed organisations might expect to undertake. These roles are significant and likely to be time-consuming, given that there will be an intensive initial establishment phase requiring many decisions and that initially there is unlikely to be substantial employee assistance. Board members, therefore, will need to have adequate capacity to fulfil their role in providing leadership and direction to the emerging scheme.

The AICD guidance also suggests careful attention to achieving a balance of skills and experience in organisational governance and an ability to contribute constructively to collective decision-making in the interests of the organisation. The guidance also emphasises the importance of avoiding the emergence of factionalism within a board structure and the attendant need for board members to put the needs of that organisation above the interests of any other organisation with which they may be affiliated. Interested applicants for board positions who have affiliations with stakeholder organisations (likely to be the situation for most applicants) will need to consider this issue carefully. This situation would be mitigated by the AICD recommendation of including a minimum of two independent board members.

Advisory structures – broad-based

In addition to the significant core roles and duties that will be required of the governing board in order to establish the organisation and its day-to-day operation (as described by the AICD), the board will need to oversee the preparation of a range of structures and products (i.e. one-off and ongoing projects) to support the effective and credible implementation of the certification scheme. These projects will include (but not be limited to) the following:

- Development, testing and ongoing review of a range of assessment mechanisms suited to a range of professional levels as required by the scope of the scheme
- Refinement of the CBS framework (initial and ongoing)
- Certification member support structures

- Documentation and analysis of applicant entry qualifications
- Assessment and endorsement of acceptable continuing professional development activities for each level of certification
- Audit processes for certification
- Sanctions
- Stakeholder engagement/strategic planning
- Preparation of competency-focussed development and testing materials (where there are no suitable existing resources)

Each of these activities is potentially complex and will require regular stakeholder engagement in order to ensure the suitability and acceptability of what is proposed by the governing board. There will be other formal committee responsibilities requiring the participation of board members, such as for risk assessment and management and audit responsibilities.

Stakeholders from all scientific disciplines and certification levels, as well as employers, unions, consumers and quality standard setters, will be very likely to take a keen interest in the development and oversight of one or more of these activities and this participation. And, given the anticipated financial constraints that could be faced during the set-up phase of the certification scheme (and associated lack of funding for paid project work), the voluntary input of these various stakeholders should be encouraged and facilitated by the governing body.

The workshop participant group agreed that the direct relationship with consumers for the medical laboratory science profession was understandably limited, yet there was acknowledgement that the potential impact on consumers of their professional work was critically important and that it is usual practice for other health professions to include a representative. At a minimum, the inclusion of a consumer representative as part of the scheme's governance arrangements would give the certification process some parity with other health profession certification governance arrangements as well as legitimacy and seriousness of intent in the eyes of the funders of medical testing in relation assuring the public of commitment to high standards of professional practice and minimisation of risk.

Discipline-specific advisory structures

In addition, stakeholders have called for the inclusion of at least a minimum level of discipline-specific competency-based certification and this will require the input of relevant experts from the disciplines involved. Participants at the workshops and in the Delphi Conference have acknowledged that advisory structures will be required to support the Board for this aspect of the certification arrangements. Such advisory structures will need to reflect core discipline interests and provide a source of content-specific advice in relation to discipline-specific scopes of practice. An advisory structure for a specific discipline may also require the cooperation of more than one association that is focussed on the same or similar discipline.

83% of Delphi Conference participants agreed that input from expert advisory groups on the scope and content of the certification framework would be appropriate and necessary (whether they were established as newly constructed groups or drew on existing expert advisory structures e.g. existing professional association structures). 83% of respondents to the Delphi Conference supported the possible adoption of

the UK biomedical scientist registration scheme classification framework[18] (operated by the UK Institute of Biomedical Science - IBMS) for structuring its discipline-specific content. The IBMS has established advisory panels in the following specialties for providing expert input:

- Cellular Pathology
- Clinical Chemistry
- Cytopathology
- Haematology
- Immunology, including representatives from Histocompatibility and Immunogenetics
- Medical Microbiology
- Transfusion Science
- Virology
- Genetics and Fertility Science (note: proposed addition from the Delphi Conference).

A successful and sustainable certification scheme would ideally have a core of uniformity while also allowing for some degree of diversity. Workshop participants noted that there may be value in promoting scheme participation by a range of professional associations in terms of assisting with sustainability of the scheme and drawing attention to the scope of professional medical science in Australia. However, in order for the scheme to be successfully integrated and focussed on its core objectives, stakeholders agreed that the professional roles of potential invitees would need to be well-aligned and similar; for example defined as "medical laboratory scientist". The role of research scientist, it was agreed, is not sufficiently aligned for inclusion. Conversely, there is a strong degree of alignment between the work of the scientific workforce in pathology laboratories and the work of the scientific workforce in assisted reproduction laboratories.

In the course of achieving successful alignment of aims and structures of the proposed scheme, there may be some marginal adjustments to be made to make the scheme workable across all disciplines. For example, there may be some initial misalignment in terms of preferred terminology – the title "medical laboratory scientist" would be acceptable to fertility scientists/embryologists, whereas a title that includes the term "pathology" probably would not be acceptable, due to the nature of their core work which is undertaken with living embryos.

Ownership of the organisation

If a company structure is selected as the vehicle for establishing the certification scheme's organisational structure, decisions will need to be made about ownership of the entity. The concept of shareholding by existing professional organisations has been discussed during consultations and been supported. Applications for shareholding by approximately 10 professional associations initially appears likely.

Consideration will need to be given to the value of the shares and associated financial contribution to the new organisation for the purchase of those shares. Given that stakeholders have spoken against the concept of proportional influence on the organisation according to existing memberships, it may be that the

[18] Note: This classification is only relevant for ensuring some consistency of competency domains with peer certification schemes and to guide the need for associations within a discipline area's need to work together to create certification guidance. Other than this constraint, it is proposed that the inclusion of discipline-specific certification options would only be limited by the relevant group/s' willingness to support the development and maintenance process.

contribution level that is feasible for the smallest/least financially capable organisation becomes the benchmark for all shareholder contributions. Most non-publicly listed companies practice an equivalent vote value for all shareholders, regardless of relative amount of shareholding.

Proposed position

Using the expertise that would be built into its advisory structures, the new certifying body and its governing board should be regarded as the ultimate source and arbiter of the competency standards that would form the basis of the new certification framework (working with the relevant associations to collate and refine over time the multiple and potentially conflicting number of individual member standards that may currently apply). This standard-setting would be based on advice from advisory committees specifically established for this purpose.

It is proposed that a new independent governing body be set up as a limited (by guarantee) liability company. 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).

The proposed structure of the governing board of the certification body made up of eight or nine[19] directors as follows:

- an Independent Chair
- participation of between four to seven suitably experienced nominees from the professional associations that have become shareholders in the Accreditation (Certification) Body - on an agreed rotational basis, which may be assisted by an agreed approach to a broad grouping of scientific practice specialisation
- one additional independent member.

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 an Advisory Board that includes this expertise. Likewise, a well-constituted and supported Advisory Board 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.

Each shareholder would be entitled to nominate a single representative to be considered for a position on the Board. All shareholder nominees would be required to act independently of their nominating body and to be appropriately trained to undertake their role as a Board member according to the relevant legislative requirements of that role. The financial contribution associated with becoming a shareholder of the company needs further consideration. No matter what support contributions might be agreed, the majority of stakeholders agreed that all shareholders should be given equal standing in terms of their capacity to

[19] The previously proposed maximum number of board members (12) is very high for an organisation of the size proposed for this scheme. With the introduction of a Standing Advisory Board and accessibility of shareholder status for all participating professional associations, the recommended board size has been reduced to maximise its capacity for efficient functioning.

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

contribute guidance to the scheme and its operation and limited financial capacity should not be an excluding factor.

It is proposed that all board members 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). Independent directors would require financial remuneration. The day-to-day management of the scheme might 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.

A Standing Advisory Board will be established, 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 Board 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, technical officers, pre-certification scientist, scientist, senior scientist[20] and clinical scientist (as per NPAAC definition for supervision of clinical aspects of the testing process) – 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 current proposed timeframes for scheme start-up and initiation are as follows:

- 31 March 2019 - Commitment from quorum of participating stakeholders to endorse the establishment of the proposed scheme
- 1 July 2019 - Commencement of preparation phase of the certification scheme, under interim governance arrangements
- 1 July 2020 (or earlier if all arrangements are in place and agreed) – Receipt of initial applications for certification under grandfathering arrangements
- 1 July 2023 – Recertification process commences for existing members; grandfathering arrangements for entry cease.

Interim governance arrangements are yet to be confirmed but will be discussed with each stakeholder organisation during finalisation of the scheme's draft Implementation Plan, which is being prepared by the HCA team. In advance of the establishment of a company and associated structure for incorporation, it is proposed that an association be formed, made up of all willing professional organisations. Given that some

[20] This level requires further discussion – see Levels of Certification section above.

associations have a higher number of potential certification applicants than others and therefore greater initial access to the views of those individuals, it is proposed that some relativity be given to voting rights for those organisations on key remaining decisions in this interim period. This approach is consistent with the approach taken to the Certification Project participation. A similar level of contribution to the activity of working groups in the preparation phase might also be anticipated, though all stakeholders should have the opportunity to participate if they desire to do so and have the necessary capacity.

The construction of the final governance arrangements will need to focus first and foremost on fair and independent governing practice for the new scheme so as 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).

One model/option for consideration is that organisations with membership numbers over a pre-determined number of actual or potential scheme applicants be free to nominate an additional governing board member (subject to the normal rules of election by the broader shareholder group), with the remaining board membership being made up of independent board members, along with members with knowledge and understanding of the needs of other professional organisation memberships (either on a rotational or voting-selected basis). 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 in order to reduce the risk of discussions getting “stuck” prematurely.

8. Sanctions

Discussion

Clear sanctions and policies for certification form part of the accountability and governance structures of a system. This includes sanctions that detail penalties for not meeting recertification requirements, such as time limits for completing assessment for certification (Ayres et al., 2009) or processes for appealing certification decisions.

Common appeals for certification programs may include (Knapp, 2000):

- refund of fees
- appealing test scores
- inadequate or inappropriate testing conditions
- requests to review assessment materials and scores.

Sanctions will be highly dependent on the final design of a certification scheme in particular the participation and entry requirements. In response to the workshop survey, the majority of participants strongly agreed that assessment outcomes should be audited and the majority also indicated that a sanctions mechanism should be accompanied by an appeals mechanism. A closer examination or consideration of the details of the sanctions process found that less than half of the participants felt that an individual could seek a review of the assessment processes, while the option to appeal a decision to apply sanctions was favoured by the majority of participants.

Figure 6 also indicates that most respondents favoured a professional development approach to sanctions. In the first instance of applying a sanction, there was a preference for individuals to be provided with counselling (67%) or supervision (67%).

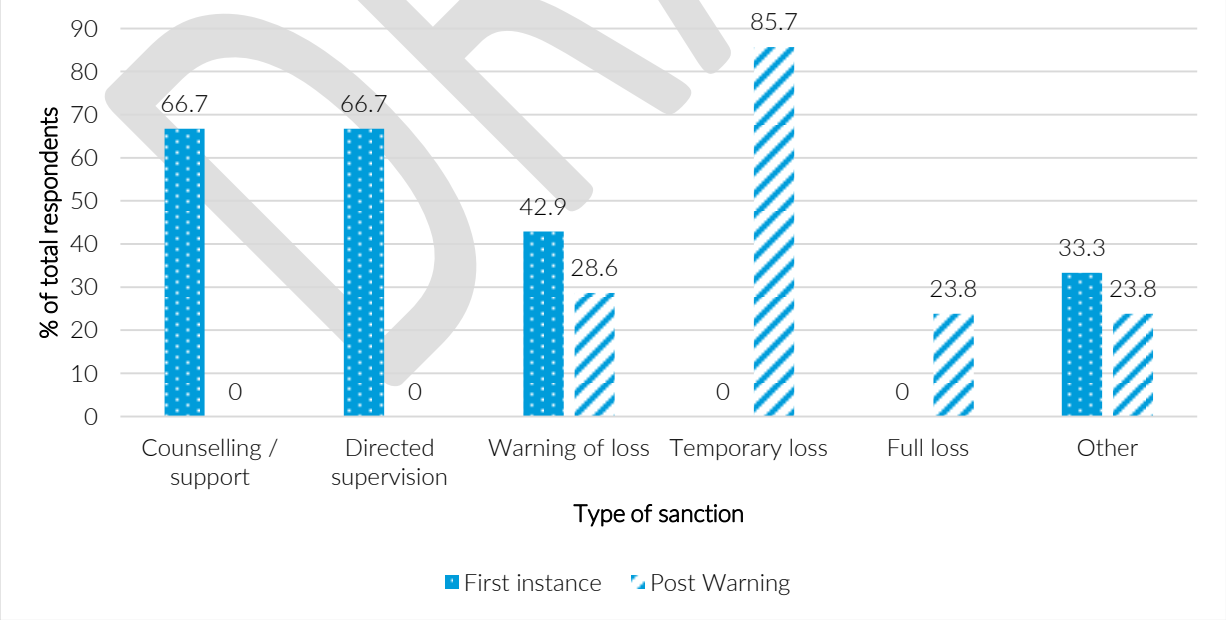

Figure 6: Comparison of type of sanctions to be applied at first and post instances of non-compliance

Subsequent instances of non-compliance with certification requirements (for instance insufficient competence at an audit, practice endangering patient safety), more stringent sanctions were favoured with temporary (86%) or even full loss (24%) of certification being considered appropriate.

Auditing process

Any form of sanction would be dependent on the process of auditing. The auditing process would need to balance cost effectiveness and sustainability with credibility and authority. The American Society for Clinical Pathology Board of Certification, for example, reviews and audits a certain percentage of randomly selected individuals who have submitted declaration forms for the Credential Management Program to verify continuing competence. As described in the *US Credential Maintenance Program Booklet* (2018), individuals are notified by mail and requested to submit supporting evidence they have previously submitted for recertification. This might include:

- Official Transcript (no copies) of formal college/university coursework
- Title page of publication and table of contents containing author name for an authored book or book chapter, doctoral dissertation
- Letter from organisation verifying participation, in what capacity and dates of service on an examination committees, committees or boards related to the profession.

The auditing process for the proposed certification scheme would most likely be undertaken by designated reviewers working on either a voluntary or paid basis (see 'Methods of Assessment' section). This level of independence from the initial competency assessment would be especially necessary if the original assessment was undertaken by a supervisor or re-certification largely relied on administrative processes.

The governing body or a delegated structure (sub-committee etc.) would be best placed in terms of the knowledge of the workforce and scheme requirements and ultimately has responsibility overseeing the process.

Proposed position

Given that compulsory participation is not a feasible option for the proposed certification scheme at this point in time, the primary purpose of sanctions will be to protect the credibility of the scheme in order 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:

a. 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
b. notification of misconduct – the Certification Board becomes aware of an incident of proven misconduct[21] 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]
c. permanent removal from the certification scheme would require unanimous agreement by the Certification Board
d. 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.

It is recommended that 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 in regard to 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. Sanctions will then be aligned with the procedures of the final scheme arrangements but it is agreed by all stakeholder groups that the key roles of sanctions should be to protect the credibility of the scheme in its objectives to ensure that minimum

[21] Where that misconduct violated competence requirements of the competency framework.

[22] Note: it was proposed that it would not be the responsibility of the Certification Board to conduct additional investigations.

standards of professional conduct are identified and preserved. "Conduct unbecoming of the profession" should not be tolerated in professionals certified under this scheme but further discussion and consideration is required in the coming months and early years of the scheme to identify how best to align the scheme's interaction with relevant health care complaints or ombudsman agencies as well as employer/worker rights and protections (sometimes conflicting) to information and/or privacy.

9. Cost of participation

Discussion

The cost of certification is dependent on a number of factors and can be one of the more difficult decisions when designing a certification system. Clearly if certification is voluntary, then the cost of certification can be one of the most common barriers to achieving certification reach within the workforce. Accordingly, some programs offer financial support to increase rates of certification (Perlstein et al., 2014).

Establishing an appropriate cost for candidates can be guided by the following factors (Knapp, 2000):

- a conservative estimate of projected volume of candidates
- building development costs of the certification system into the fee in the initial years – the amount of development costs may be dependent on whether the system was funded through grant funds or a loan
- not underestimating the ability of the market to pay, in some cases fees are too low
- recognising recertification fees as an important source of income
- recognising that development and adminstrative costs per candidate will be dependent on the complexity of assessment processes.

In the Discussion Paper (Stanford, et al., 2017), 24 professional certification schemes from Australia and several overseas countries were identified and the annual cost of certification to the individual participant were examined. Cost for initial certification ranged from a low of $130 per annum to as high as $1,000 per annum. The range of fees in this analysis (also included here at **Appendix A**) formed the basis of discussion with Workshop participants about suitable fees and possible levels of participation in a proposed certification scheme, both for initial entry to the scheme and for recertification fees.

A range of possible 'right price' estimates for initial certification were offered to participants at the first workshop for consideration. Ranging from $100 to over $400, these estimates took into account consideration of both economic viability of the scheme and the price that the workforce (by level) might be willing to bear. The median cost estimate of participants (n=21) was $200 for initial certification of workers based on what participants thought workers might be willing to pay. A much lower price of $100 was considered by most (57%, n=21) as appropriate for recertification. 74% of Delphi Conference participants also agreed that these fees would be reasonable. However, the suggested concept of a reduced fee for "early adopters" /entrants to the scheme was not well supported by stakeholders, largely on the basis that this type of exception would be likely to cause confusion and complication amongst potential entrants and be difficult to administer.

These estimates can therefore be seen to rest at the lower end of certification cost as experienced by other professions (including health professions in Australia) and the viability of the proposed scheme at this level of individual contribution would almost certainly rest on achieving a high rate of participation in the scheme.

If the size of the medical scientist[23] workforce in 2006 lay somewhere between 7,000 and 14,000 (see Ridoutt et al., 2011 for the workings behind this estimate), then the potential revenue from initial certification (at a price of $200 per applicant per annum and assuming the higher end of the range) could be as high as $2.8 million per annum (based on 100% participation). However, the reality of the likely participation patterns (at least in the initial stages) for the proposed scheme is that 100% participation could not be relied upon so a more nuanced and strategic approach to promoting financial viability of the scheme needs to be explored.

Workshop participants also emphasised the opportunity that high rates of participation would provide in terms of access to reliable workforce data. The scientific workforce of medical science laboratories shares the same challenge as the medical specialist pathologist workforce in that, despite their significant contribution to the health and wellbeing of the Australian population, their presence as contributors is very poorly recognised. In addition, the estimated size of the medical science workforce is almost certainly much higher than many of the more widely recognised and similarly expert health professions, such as dietitians, podiatrists and medical radiation technologists.

Proposed position

Cost of entry to the scheme

The cost of entry[24] to the proposed certification scheme should be kept relatively low in order 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 fee level that is consistent with the range of similar Australian health professions, such as the tax-deductible annual fee of between $300 per annum i.e. the mid-range estimate proposed by stakeholders, appears likely to be acceptable.

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 is a proposed fee structure for entering the scheme. Fees are included only for those levels of certification currently proposed for inclusion in an initial scheme.

[23] Refers to a workforce including technical officers and laboratory assistants.

[24] 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")..

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 similar to that of the initial certification process.

Financial viability of the scheme

The above proposed payment schedule can be used to form an estimate of the certification scheme income. The 2011 study of the workforce in Australian medical pathology laboratories (Ridoutt et al., 2011) adopted the following occupational category proportions from the 2010 survey of the workforce (Urbis, 2010):

- Senior medical laboratory scientists[25] (3.6% of the total estimated number in the medical pathology scientists workforce[26]);
- Medical laboratory scientists (50.0%);
- Medical laboratory technicians (21.4%); and

Using these proportion estimates and applying to the total workforce estimate of 14,000, adding in phlebotomists (estimated number of 1,800), and assuming an initial participation uptake rate of 30% to be achieved by the end of the first 3 years (the most popular estimate of the Workshop participants), a possible income for the scheme at the point of introduction of certification 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**

[25] As defined by NPAAC (2007) and based on the definition included in the Health Insurance Act 1973

[26] This data obtained from the employer survey data of the National 'Survey of the Pathology Workforce' (Urbis, 2011)

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 (assuming immediate uptake of the scheme by this estimated portion of the eligible population but more likely to occur as an incremental increase of participation over time). The successful operation of the scheme would clearly benefit from maximum rather than minimum participation levels.

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).

Seed funding from professional associations and societies might take the form of an initial lump sum from each association proportional to the number of their members. Almost 70% of Delphi Conference respondents felt that approximately $10 or more per member could be contemplated but further stakeholder discussions acknowledged that, if there was not adequate enrolment in the scheme, a $10 per member level of contribution may not be sufficient to support the initial operation of the scheme.

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 available to 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 array of CPD activities that can be easily and cheaply accessed by TOs throughout Australia.

The certification scheme's greatest opportunity for financial success and viability rests on the initial and ongoing widespread participation of potential applicants and stakeholders will play a large role in promoting the value of the scheme to their members, other colleagues and employers. However, there is a significant body of work still to be done during the preparation phase and this work will need funding support prior to the availability of applicant fees. Stakeholder organisations will therefore be encouraged to consider their capacity to offer support in the form of funding and/or in-kind contribution to assist during the start-up and early operating phase, with similar principles of relative representation in the interim governance arrangements providing broad guidance for relative contributions. Budget calculations and in-kind support requirements for this start-up period will be estimated as part of finalising the Implementation Plan.

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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/ accreditation arrangements

Profession	Point of entry	Competency based Framework (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 employment Full 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

Profession	Point of entry	Competency based Framework (Y/N)	CPD – competency based (Y/N)	More than one level of certification (Y/N)	Annual fee
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) PLUS IPA – accredited degree plus fee-paying post grad qualification required (Deakin University) or CPAA – 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

Appendix C: Draft list of high priority potential risk areas dealt with by medical scientist competence

The key public safety and quality risk areas from the current Australian competency framework (and which also underpin quality professional practice) that were identified by the relevant stakeholder workshop discussion group for inclusion in an initial certification scheme were:

(1) Pre-analytical

(*all six identified competencies are important for laboratory procedures relating to proper patient identification and ensuring testing* quality - eg ensuring the appropriateness of sample collection procedures, the correct identification of patients/specimens/fertility-related material, and safe transport of testing samples or embryology material)

(2) Correlation and validation of results

(eg *2.1: Assess the validity of data / results against possible range of outcomes;* identify error early and reduce the risk of having to retract results from clinicians/patients due to errors in the testing process)

(3) Interpretation, reporting and issuing of lab results

(eg *3.3: Ensure that results with important diagnostic or treatment implications are communicated as per established protocols*; biggest issue here is the risks around communication of high risk results; according to data from the KIMMS program, in 20% of labs communication is done by scientists but all scientists need to understand and act to ensure escalation for clinical review as required).

(4) Maintenance of laboratory documentation, equipment, and resources

(eg *4.2: Maintenance of laboratory equipment* – if responsibility for ensuring the proper maintenance and operation of testing equipment is not taken, the risk of undetected incorrect testing/laboratory procedures due to equipment malfunction is increased)

(5) Safe work practices (responsibility for the safety of self, colleagues and the testing process in general)
(eg *5.2: Respond to unsafe work practices - not just about public safety but also about staff);*

5.3: Ensure correct procedures are followed for acquisition, collection, storage, transportation and disposal of biological, toxic and radioactive wastes)

Other potentially high risk elements in the competency framework for consideration in the certification model

(6) Professional development

6.4 Recognise own abilities and level of professional competence

6.5 Comply with profession's code of ethics

(7) Accountability

7.1 Accept responsibility for own actions/omissions

7.2 Make independent, professional judgements

7.4 Demonstrate knowledge of new tests and their potential in the laboratory

(8) Communication

8.1 Participate in quality improvement activities

8.2 Continually review laboratory processes and testing to streamline, minimise waste and increase efficiency

(9) Education / Training

9.4 Train personnel in the operation of instruments and equipment, the performance of methods and quality control procedures, patient confidentiality, and the observation of safety measures.

"Professional competence = Initiative + knowledge (professional contribution above and beyond basic training)"

Summary of Delphi Conference input:

Competency	Specific suggestions/comments on high risk issues
1. Pre-analytical/Technical Skills	Those essential for providing safe and quality results for patients in a specific discipline ie pre-analytical, analytical
✓✓✓	Sample requirements
	Patient ID
	Patient identification issues, specimen identification issues
	Sample handling
	Morphological skills
	Blood bank competencies
2. Correlation and validation of results	Understanding of the quality system, and actions to follow, when something is flagged as: i) out of control, ii) abnormal results, iii) high risk/critical results
✓✓	Any area where laboratory data has a critical impact on patient welfare
	Obligations in reporting results (eg critical results)
	Anything where skill is needed in result interpretation and validation of a report eg blood banking, genetic testing, prenatal testing, serious contamination of a CSF fluid.
	QA measures
	Quality control and quality assurance competencies
	QC
	EQA
	Those essential for providing safe and quality results for patients in a specific discipline ie pre-analytical, analytical
	Error identification
	Principles behind each assay performed so that troubleshooting an be carried out
3. Interpretation, reporting and issuing of lab results	Anything that if the scientist is the final laboratory sign-off rather than the rubber stamping of a pathologist who has accepted the results of the scientist because they are deemed competent.
✓✓	Anything where skill is needed in result interpretation and validation

	of a report eg blood banking, genetic testing, prenatal testing, serious contamination of a CSF fluid.
	Those essential for providing safe and quality results for patients in a specific discipline ie pre-analytical, analytical
	3.3: Ensure that results with important diagnostic or treatment implications are communicated as per established protocols
	Confidentiality
4. Maintenance of laboratory documentation, equipment, and resources	5.2: Identify and respond to unsafe work practices and breaches of regulations
✓✓	5.3: Ensure correct procedures are followed for acquisition, collection, storage, transportation and disposal of biological, toxic and radioactive wastes
5. **Safe work practices**	Workplace health and safety issues
✓✓✓	
6. Professional development	6.5: Comply with profession's code of ethics
✓✓✓	
7. Accountability	7.1: Accept responsibility for own actions / omissions
✓	7.2: Make independent, professional judgements (✓✓)
	7.3: Demonstrate knowledge of contemporary ethical issues impinging on Medical Science
	Levels of responsibility within labs, responsibilities of scientific staff
	Inclusion of awareness of privacy, patient confidentiality and IT security should be included (possibly with Accountability)
8. Communication	8.1: Participate in quality improvement activities (✓✓)
	8.2: Continually review laboratory processes and testing to streamline, minimise waste and increase efficiency
9. Education/Training	9.3: Where appropriate, provide instruction on collection, testing of specimens, interpretation and significance of results and service delivery.

Appendix D – Competency assessment tool example

NSW Biochemical Genetics Service Competency Assessment

a) direct observation of routine work processes and procedures, including all applicable safety practices
b) direct observation of equipment maintenance and function checks;
c) monitoring the recording and reporting of examination results;
d) review of work records;
e) assessment of problem solving skills;
f) examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.

Unit	Element	Criteria for assessment *(Items in red italics for Senior Staff only)*	Evidence type :	Evidence, Workstation(s) assessed	Date of assessment	Sign-off	Reassess-ment due
1: Collection, preparation and analysis of clinical material	1.1	Follows instructions in sample reception manual.					
	1.2	Ensure the appropriateness of specimen reception procedures as per manual.					
	1.3	Evaluate specimen suitability prior to analysis as per manual.					
	1.4	Prioritise tests according to clinical information.					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	1.5	Process specimen utilising appropriate techniques selecting control materials etc as per manual.					
	1.6	Test data, calculations, results and acceptance/rejection of analytical procedure outcome as per manual.					
2: Correlation and validation of results of investigations using knowledge of method(s) including analytical principles and clinical information							
	2.1	Correlation and validation of results of investigations using knowledge of method(s) including analytical principles and clinical information.					
	2.2	Validation of results					
	2.3	Make decisions about reporting results, repeating procedures, consulting senior staff and carrying out further tests as per manual.					
3: Interpretation, reporting and issuing of laboratory results							
	3.1	Verify report(s) with sample identification (vial checks etc)					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	3.2	Use the administrative systems in place to communicate the results. Telephone and fax results issued as per manual.					
	3.3	Ensure that results with important diagnostic or treatment implications are communicated as per established protocols					
	3.4	Ensure appropriate storage of data as per manual.					
4: Maintenance of documentation, equipment, resources and stock							
	4.1	Coordinate supplies of stocks and reagents as per established protocols. Record date of opening of reagents etc.					
	4.2	Participate in maintenance of the laboratory and equipment. Perform PM as per manual.					
	4.3	Participate in preparation and revision of manuals and protocols. Uses suggestion sheets to identify required amendments.					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	4.4	*Ensure appropriate resources are available to the laboratory*					
5: Maintenance and promotion of safe working practices							
	5.1	Prepare, label and store reagents and solutions as per manual.					
	5.2	Identify and respond to unsafe work practices and breaches of regulations. Participate in monthly inspections.					
	5.3	Ensure correct procedures are followed for acquisition, collection, storage, transport-ation and disposal of biological, chemical, and toxic wastes					
	5.4	Respond appropriately to emergency situations, maintain currency of mandatory training.					
6: Professional accountability and participation in continuing professional development							
	6.1	Establish and communicate personal goals in professional development during annual performance review.					
	6.2	Maintain and update scientific/technical knowledge					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
		and skills. Document attendance at meetings, journal club etc. *Participate in CPD schemes as appropriate.*					
	6.3	Develop skills relevant to the enhancement of professional growth. Engagement in quality improvement activities, method development, reagent evaluations.					
	6.4	Recognises own abilities and level of professional competence, appropriate referral of queries to senior staff.					
	6.5	Complies with profession's code of ethics. Complies with all departmental and hospital policies.					
7: Responsibility for professional practice including test selection, development and use of laboratory investigations							
	7.1	Accepts responsibility for own actions/omissions. *Tasks are delegated to staff commensurate with their abilities and scope of practice.*					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	7.2	Performs analytical and decision making functions without supervision. *Responsible for or contributes to strategic direction of laboratory*					
	7.3	Demonstrates knowledge of contemporary ethical issues impinging on Medical Science. Unprofessional conduct is identified and dealt with or notified accordingly.					
	7.4	Development of new tests in the laboratory as per established protocols. *Demonstrates innovation and highly developed and specialised skills*					
8: Liaison with health workers and others to continuously improve the service							
	8.1	Participate in quality improvement activities					
	8.2	Continually review laboratory processes and testing to streamline, minimise waste and increase efficiency. Improvement suggestions made through established process.					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	8.3	*Establish and maintain relationships with suppliers*					
	8.4	Establish and maintain professional relationships with service users. *Key performance indicators (identified by discussion with the users of the laboratory service) are agreed and monitored by the laboratory to ensure that the laboratory service meets the needs of its clients.*					
9: Participation in education and training of health workers and others							
	9.1	Research, prepare and deliver appropriate presentations					
	9.2	Participate in interdepartmental and other meetings (WSGP presentations etc.)					
	9.3	Where appropriate, provide instruction on collection, testing of specimens, *interpretation and significance of results*					

Unit	**Element**	**Criteria for assessment** ***(Items in red italics for Senior Staff only)***	**Evidence type :**	**Evidence, Workstation(s) assessed**	**Date of assessment**	**Sign-off**	**Reassess-ment due**
	9.4	Train personnel in the operation of instruments and equipment, the performance of methods and quality control procedures, patient confidentiality, and the observation of safety measures					
10: Contribution to advancement of knowledge and improvement of laboratory practice							
	10.1	Contribute to planning and design of research and development projects					
	10.2	Follow research/development protocol					
	10.3	Evaluate results and the need for further experimental work					
	10.4	Prepare and deliver report					

Appendix E: UK Code of Conduct for Biomedical Scientists (2014) - example

Purpose

The Code consists of principles, which Institute members are expected to observe in the interests of patients care and in order to promote confidence in the profession of biomedical science.

Code of Conduct

A member of the Institute of Biomedical Science will:

1. Professionalism

1.1 Uphold the name and reputation of the Institute of Biomedical Science and the biomedical science profession and practice according to its responsibilities, standards, ethics and laws

1.2 Maintain the highest standards of professional practice and act in the best interests of patients, the service and other professionals

1.3 Respect the confidentiality of patients, employer, and service users unless disclosure is permitted by law and justified in the patient's interest

1.4 Not practise, nor impose upon others to practise in conditions where professional integrity, standards and laws would be compromised

2. Competence

2.1 Understand and work within the limits of their professional knowledge, skills and experience

2.2 Never delegate a task or duty to anyone who is not trained, qualified or experienced sufficiently to undertake it without supervision

2.3 Ensure that colleagues under their management are fully supervised and supported

2.4 Exercise and continually develop their professional knowledge and skill throughout their professional life

2.5 Communicate effectively and meet all applicable reporting standards

3. Behaviour

3.1 Not allow bias, conflict of interest, or the undue influence of others, override their professional judgement

3.2 Take action without delay if patient safety or service delivery is at risk according to local and national 'whistleblowing' guideline

3.3 Treat all patients, service users and colleagues respectfully and equally without any discrimination or prejudice that could compromise their professional roles or duty of care

3.4 Cooperate with employer and professional colleagues in the interests of providing a safe and high-quality service.

Creating workforce solutions

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