

National Certification Scheme for Medical Laboratory Scientists

Discussion Paper
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HUMANCAPITAL

Alliance

Creating workforce solutions

This Discussion 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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Contents

Executive summary	4
Aim of the project	4
Background	4
Certification scope	5
What is certification.....	5
Certification scheme elements	5
Next steps/summary.....	7
Acronyms & abbreviations.....	8
1. Background and rationale for the project.....	10
The case for certification	10
History of the pursuit of certification	11
The aim of certification	11
Where the discussion paper fits	13
2. Scope of the project.....	14
<i>NPAAC role definitions</i>	<i>14</i>
<i>Australian & New Zealand Standard Classification of Occupations (ANZSCO) role definitions</i>	<i>15</i>
<i>Competency based standards for scientific workforce of the pathology laboratory.....</i>	<i>16</i>
<i>Sub-specialty scope of practice</i>	<i>18</i>
3. Typical elements of professional certification models	20
Defining certification.....	20
Features of a certification system.....	21
<i>Founding principles</i>	<i>21</i>
<i>Core elements</i>	<i>21</i>
4. Current Australian context of health profession quality assurance	26
Different quality assurance approaches	26
Regulatory approach.....	27
Self-regulation approach	28
Current pathology laboratory quality assurance approach.....	29
5. Selected certification case studies.....	30
Australian health profession certification schemes.....	30
<i>Dietitians</i>	<i>30</i>

<i>Exercise scientists and physiologists</i>	33
<i>Genetic counsellors</i>	35
<i>Health Informaticians</i>	38
Overseas case study examples.....	41
<i>Relevant US schemes</i>	41
<i>United Kingdom</i>	44
<i>South Africa</i>	45
Summary of case study examples.....	47
6. Assessment – how could that work?	51
7. Factors that could influence scheme success	55
References	57
Appendix A: Comparison of professional certification/ accreditation arrangements	60

Executive summary

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. The specific objectives of the research 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
2. engage the relevant scientific professional organisations in effective collaboration
3. craft initial consensus on possible way forward amongst all pathology laboratory stakeholders on a professional certification model that is objective, evidence-based and sustainable
4. identify and address any outstanding stakeholder reservations in relation to the acceptance of a certification model
5. provide a clear map to future action through an implementation plan.

The aim of this discussion paper is to provide an evidence base and direction for discussions to be held with all stakeholders at a Workshop on 27 November 2017.

Background

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

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

This discussion paper outlines the findings of a literature review of relevant national and international professional certification models, including key elements of professional certification schemes for consideration.

Certification scope

In considering certification arrangements, workforce boundaries must firstly be defined to have a clear understanding about who is affected by a workforce intervention. Certification schemes most often cover precisely prescribed single professions, but can also, and often do, cover multiple workforce categories both horizontally (many closely related occupations at effectively the same level of competence) and vertically (related occupations in a career path with varying levels of competence). The pathology laboratory scientific workforce could develop a certification scheme that was both horizontal (a range of scientist specialty areas) and vertical (technician, scientist, clinical scientist) in its scope.

Some existing workforce scope definitions can be obtained from NPAAC (vertical), the Australian & New Zealand Standard Classification of Occupations (ANZSCO, vertical), and the endorsed competency based standards for the Scientific Workforce of the Pathology Laboratory (vertical). The sub-specialty professional associations also each define their scope of practice.

What is certification

Certification is frequently confused or used interchangeably with ‘accreditation’, ‘licensing’ and ‘registration’. While each are distinct systems or methods for ensuring quality standards in the delivery of services and products, certification is the formal and public recognition of *an individual’s* experience, knowledge and qualifications according to pre-determined standards. Additionally, certification provides portable credentials that belong to and move with an individual (Knapp, 2000; Ingvarson, 2014).

Certification scheme elements

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:

- **Participation requirements** – is the scheme participation voluntary on the part of workers or made mandatory by government intervention (e.g. legislation) or employer requirements
- **Competency standards** – is the scheme based on academic qualifications or on a more detailed description of competency requirements, or both. And if on specially developed competencies, what is the source of authority for their development and maintenance.
- **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)

- **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
- **Methods of 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
- **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
- **Accountability and governance** – what are the structures and processes, such as by-laws, board members and administrative systems, that need to be implemented to ensure independence and sustainability
- **Sanctions** – what are the penalties and processes for non-compliance of the certification system as well as appeals processes and conditions
- **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).

Analysis of the case study certification schemes and the literature suggests some elements are more important than others to the success of any scheme implementation. They are:

- Providing scheme participants with a sense of professional **pride and public recognition** of the extent of workforce effort that lies behind the professional processes
- Tangible **economic benefits** in terms of a market presence and / or access to third party payment structures
- Providing **consumer protection and confidence** in services. The same might be said for employers (as more direct ‘consumers’ for instance of a certification scheme with an associated register of certified practitioners). Processes of assessment and recertification are important in engendering and retaining confidence
- Overt **commitment to agreed competencies** – upon entry and over the course of professional life
- Processes for **identifying non-compliance** with the conditions of certification and applying relevant sanctions.

As some case studies and stakeholder interview subjects have indicated, if a certification scheme is to be attempted it must be highly credible in terms of its perceived integrity, its validity and reliability in terms of measuring competence, and in the way it identifies and deals with non-compliant behaviour and deficiencies in competence.

Next steps/summary

The discussion paper is intended to form the basis of progressively prescriptive 'position papers' that flesh out more detail of any proposed certification scheme and increasingly reflect stakeholder rather than researcher perspectives. The broad timeline for the project is outlined below:

Project activity	Timeframe
Literature review	July – September 2017
Discussion paper circulated	November 2017
Stakeholder interviews	October-November 2017
National workshop	27 November 2017
Position paper prepared and circulated	December – February 2018
Stakeholder input (Delphi technique)	February - March 2018
Revised position paper circulated	April 2018
Discipline-specific consultations	April – June 2018
Position paper refined and agreement sought	July 2018
Draft implementation plan circulated	October 2018
Implementation plan revised	December 2018

Acronyms & abbreviations

AACB	Australasian Association of Clinical Biochemists
ACHI	Australasian College of Health Informatics
ACS	Australasian Cytometry Association
ADC	Australian Dietetic Council
AEP	Accredited Exercise Physiologist
AES	Accredited Exercise Scientists
AHMAC	Australian Health Ministers' Advisory Council
AHPRA	Australian Health Practitioner Regulation Agency
AIMS	Australian Institute of Medical Scientists
AMT	American Medical Technologists
ANZSCO	Australian & New Zealand Standard Classification of Occupations
APD	Accredited Practising Dietitian
APRN	Advanced Practice Registered Nurses
AQF	Australian Qualification Framework
ASCP	American Society for Clinical Pathology
ASGC	Australasian Society of Genetic Counsellors
CAT	Computer adaptive testing
CHIA	Certified Health Informatician Australasia
CME	Continuing Medical Education
COAG	Council of Australian Governments
CPD	Continuing professional development
DAA	Dietitians Association of Australia
DCC	Dietetic Credentialing Council
DSR	Dietetic Skills Recognition
DVA	Department of Veterans' Affairs
ESSA	Exercise and Sports Science Australian

FTE	Full-time equivalent
HCPC	Health and Care Professions Council
HGSA	Human Genetics Society of Australasia
HIMAA	Health Information Management Association of Australia
HISA	Health Informatics Society of Australia
HPCSA	Health Professions Council of South Africa
IBMS	Institute of Biomedical Science
IPMA	International Project Management Association
MOPS	Maintenance of professional standards
NASRHP	National Alliance of Self-Regulating Health Professions
NATA	National Association of Testing Authorities
NCS	National Competency Standards
NCSBN	National Council of State Boards of Nursing
NPAAC	National Pathology Accreditation Advisory Council
NRAS	National Registration and Accreditation Scheme
PAC	Pathology Associations Council
PAI	Principals Australia Institute
QUPP	Quality Use of Pathology Program
RCPA	Royal College of Pathologists Australasia
SIG	Special Interest Group
SMLTSA	Society for Medical Laboratory Technologists of South Africa
THANZ	Thrombosis and Haemostasis society of Australia and New Zealand

1. Background and rationale for the project

The case for certification

This project builds on previous investment under the Quality Use of Pathology Program (QUPP) on pathology scientific workforce career pathways¹ (and developments that have occurred since, utilising the resource material developed). The Career Pathways project identified elements of the career pathway where ongoing professional development, primarily on-the-job, leads to genuine competence enhancement of scientists and the Vocational Education and Training (VET) trained (technical support staff) workforce, and that increase in capability required appropriate recognition.

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

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

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

Currently it is a requirement that all laboratory staff have assessment of competence at regular intervals (ISO 15189 5.1.6, and referenced under the overarching 2013 NPAAC standards document *Requirements for Medical Pathology Services* mentioned above) – however, it is difficult for a laboratory to independently audit such assessments. Accordingly, the National Association of Testing Authorities (NATA) accreditation assessment processes which apply to staff competence are potentially flawed, largely dependent as they are on both peer-assessments during a limited window of engagement, and an assumption that the relevant employer has adequate insight and skill to assess the competence of its scientific workforce effectively.

¹ Human Capital Alliance (2011) *Career Structures and Pathways for the Scientific Workforce in Medical Pathology Laboratories – Final Project Report*. Report commissioned by the Department of Health and Ageing, July

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

History of the pursuit of certification

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

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

A number of the other health professions similarly placed have initiated self-regulation², in the form of certification of their membership for entry and (to a greater or lesser extent) maintenance of professional competence.

The aim of certification

The pursuit of certification, to be defined more precisely later in this paper, is an attempt to primarily establish and recognise minimum standards of scientist competence (certification) that are aimed at minimising professional practice error, particularly error based on any competence deficit of scientists (and technicians). A certification model for the scientific workforce would address the QUPP objective related to Quality Pathology Practice – that 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”.

Insofar as a more competent workforce generally is more adaptable and capable of responding faster and more appropriately and flexibly to changes in service demands (inspired by consumer

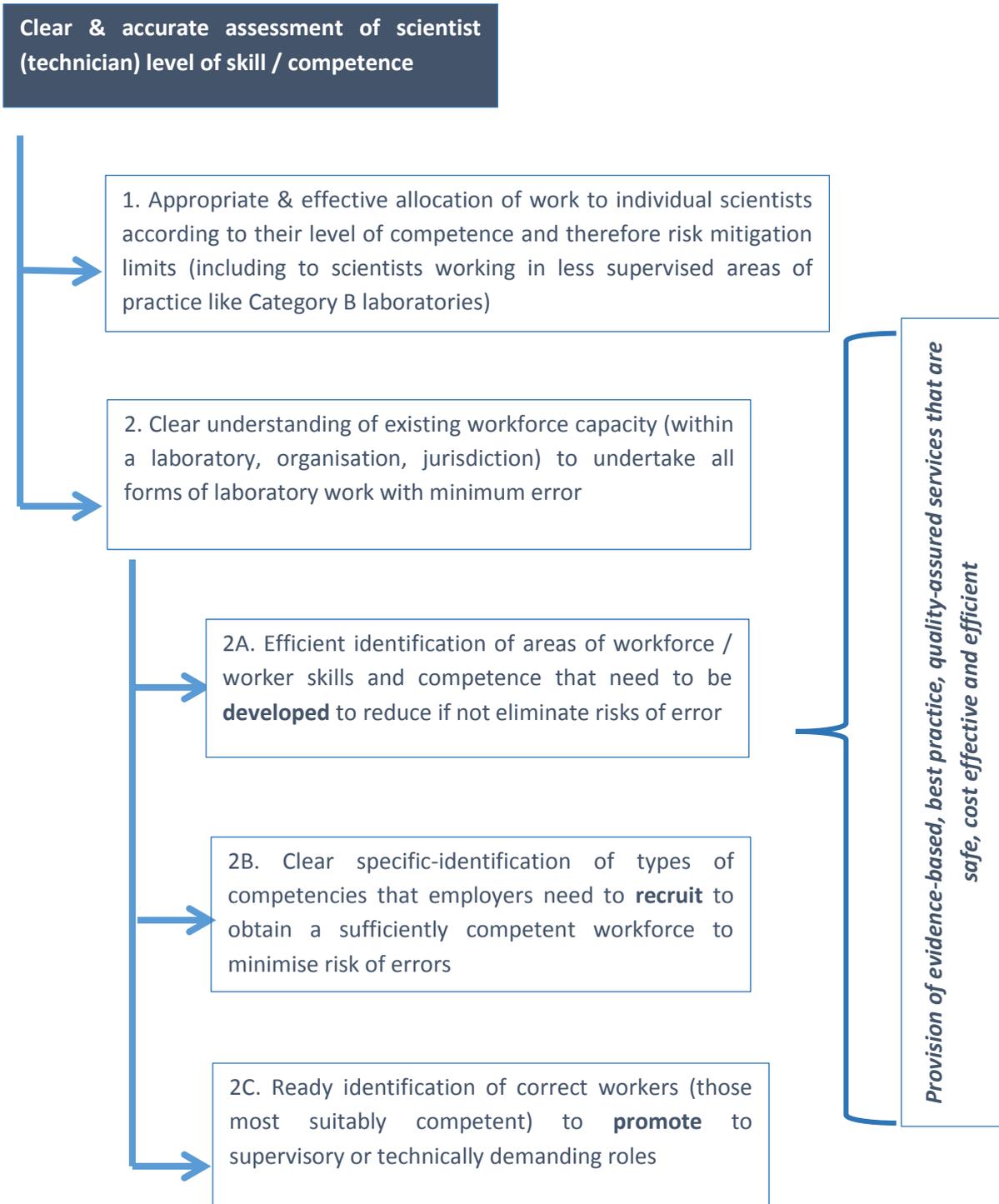
² See for instance membership of the National Alliance of Self-Regulating Health Professionals (NASRHP) ... <http://nasrhp.org.au/>

focused demands), then certification may also satisfy QUPP Objective 1 and deliver higher quality consumer services.

The ‘logic’ between certification and the desired outcomes of QUPP Objective (3) and (1) is developed in Figure 1. The logic also strongly suggests other potential human resource management benefits from certification (especially if competency based) including for recruitment, promotion, training efficiency and even workforce planning.

Figure 1: Proposed logic between proposed intervention and outcomes

Certification delivers ...



Where the discussion paper fits

The specific objectives of the research 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
2. engage the relevant scientific professional organisations in effective collaboration
3. craft initial consensus on possible way forward amongst all pathology laboratory stakeholders on a professional certification model
4. identify and address any outstanding stakeholder reservations in relation to the acceptance of a certification model
5. provide a clear map to future action through an implementation plan.

The discussion paper is intended to address Objective (1), and in so doing provide a strong platform for engagement with industry organisations (Objective [2]). As the project progresses the discussion paper will form the basis of progressively prescriptive ‘position papers’ that flesh out more detail of any proposed certification scheme and increasingly reflect stakeholder rather than researcher perspectives. The broad timeline for the project is outlined below.

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2. Scope of the project

In any study of the workforce, but especially any consideration of certification arrangements, it is critical to precisely define the workforce boundaries – to be clear about who is affected by a workforce intervention. Investigating certification of health professionals in France, Matillon et al. (2005) suggest that the minimum prerequisite includes:

“All professions are accurately defined, in consultation with the professionals themselves and in the context of the requirements of the working environment.”

The medical pathology laboratory scientific workforce is characterised by multiple job titles and multiple skill levels, and has only broad guidelines and general conventions govern employment decisions. It is accordingly difficult to draw precise boundaries around the workforce which is the subject of this study. In the following sections some possible parameters around the workforce scope are discussed.

NPAAC role definitions

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

The current NPAAC definitions (NPAAC Requirements for Supervision, 2007) are as follows³:

Technician⁴

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

- (i) associate degree or diploma as per Australian Qualifications Framework with subjects relevant to pathology or laboratory operations awarded by a recognised Australian TAFE or RTO
- (ii) qualification with subjects relevant to the field of pathology awarded by an overseas tertiary institution after not less than two years full-time study or an equivalent period of part-time study and where the qualification is recognised as equivalent to a diploma by the Australian Institute of Medical Scientists according to their authority approved by the Australian Education International-National Office of Overseas Skills Recognition with appropriate training and certified competencies to perform the functions required and who is authorised to perform this function by the Laboratory Director.

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

- (a) a degree in science or applied science with subjects relevant to the field of pathology awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a

³ NPAAC definitions may be subject to change with the revised *Supervision Requirements* expected to be published in the near future.

⁴ Technicians are responsible for supervising other technical staff, such as laboratory assistants.

professional class of membership of the AACB, Australian Institute of Medical Scientists, Australian Society for Microbiology, Australian Society of Cytology, Human Genetics Society of Australasia

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

(c) a qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the *Health Insurance Act 1973*, to be equivalent to a qualification referred to in paragraph (a) or (b) of this definition.

Senior scientist means a scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications:

(a) a Doctorate of Philosophy in a subject relevant to the field of pathology

(b) a Fellowship of the AACB

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

(d) a Fellowship of the Australian Society for Microbiology (medical/clinical microbiology)

(e) a Fellowship of the Human Genetics Society of Australasia

(f) a qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the *Health Insurance Act 1973*, to be equivalent to a qualification referred to in paragraph (a), (b), (c), (d) or (e) of this definition.

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

Australian & New Zealand Standard Classification of Occupations (ANZSCO) role definitions

There are relevant definitions of laboratory staff and associated roles in the ANZSCO, as shown in Box A below, and these definitions do provide more detail on the role scope.

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

BOX A

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

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

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

Competency based standards for scientific workforce of the pathology laboratory

A current set of Competency Based Standards for the *Scientific Workforce of the Pathology Laboratory* reflects the work performed by staff of different levels of qualification, skill, experience, responsibility and accountability. This framework has been developed by members of the Australian medical scientist profession and was endorsed by the Pathology Associations Council (PAC-<http://www.pathology.med.pro/PAC.html>) in 2009. The PAC includes the participation of all peak pathology professional and industry bodies and which meets on an “as needs” basis to consider issues of common concern and interest to all or several of its member bodies. The competency framework has also been individually endorsed (and in some cases published) by PAC member bodies (e.g. by AIMS and AACB).

The competency framework consists of 10 units of competence, each unit having between 3 and 6 'elements'. The first six units of the competency standards of the framework represent general competencies for the medical laboratory science workforce whereas the last four represent advanced competencies expected of staff performing supervisory or management roles. It is intended that these standards be suitable for assessment of competency in a specific discipline or across several disciplines. The 10 standards are outlined in summary form in Table below.

Table 1: Competency Based Standards for Scientific Workforce of the Pathology Laboratory

1. Technical Skills

* *Collection, preparation and analysis of clinical material*

- 1.1 Ensure the appropriateness of sample collection procedures
- 1.2 Ensure the appropriateness of specimen reception procedures
- 1.3 Evaluate specimen suitability prior to analysis
- 1.4 Determine the priority of laboratory requests (triage) to effectively manage service requirements

1.5 Process specimen utilising appropriate techniques

1.6 Read and validate results

2. Knowledge Base

*** Correlation and validation of results of investigations using knowledge of method(s) including** analytical principles and clinical information

2.1 Assess validity of data / results against possible range of outcomes

2.2 Perform validation of results

2.3 Make decisions about reporting results, repeating procedures, consulting senior staff and carrying out further tests within established guidelines

3. Analytical / Decision Making

*** Interpretation, reporting and issue of laboratory results**

3.1 Verify report(s) with sample identification

3.2 Use the administrative systems in place to communicate the results

3.3 Ensure that results with important diagnostic or treatment implications are communicated as per established protocols

3.4 Ensure appropriate storage and disposal of data and reports

4. Resource Maintenance

*** Maintenance of documentation, equipment, resources and stock**

4.1 Coordinate supplies of stocks and reagents

4.2 Participate in maintenance of the laboratory and equipment

4.3 Participate in preparation and revision of manuals and protocols

4.4 Ensure appropriate resources are available to the laboratory

5. Safety

*** Maintenance and promotion of safe working practices**

5.1 Prepare and store reagents and solutions

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

5.4 Respond appropriately to emergency situations

6. Professional Development

*** Professional accountability and participation in continuing professional development**

6.1 Establish and communicate personal goals in professional development

6.2 Maintain and update scientific / technical knowledge and skills

6.3 Develop skills relevant to the enhancement of professional growth

6.4 Recognise own abilities and level of professional competence

6.5 Comply with profession's code of ethics

7. Accountability

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

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

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

8. Communication

*** 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

8.3 Establish and maintain relationships with suppliers

8.4 Establish and maintain relationships with service users

9. Education / Training

*** Participation in education and training of health workers and others**

- 9.1 Research, prepare and deliver appropriate presentations to peers in-house or externally
- 9.2 Participate in interdepartmental and other meetings
- 9.3 Where appropriate, provide instruction on collection, testing of specimens, interpretation and significance of results and service delivery
- 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. Research and Development

*** Contribution to advancement of knowledge and improvement of laboratory practice**

- 10.1 Contribute to planning and design of research and development projects
- 10.2 Follow research / development protocol
- 10.3 Evaluate results and the need for further experimental work
- 10.4 Prepare and deliver report

In the complete version of this competency framework (which can be found at <https://www.aims.org.au/documents/item/195>), each of these standards is able to be assessed according to required levels of competency, commencing with the most basic or introductory proficiency levels. In this way, different roles can be distinguished. The competencies are intended to operate cumulatively that is a scientist should be able to master competency levels which are assigned to laboratory assistants and technicians, but also master higher levels of proficiency within the same competence area.

Sub-specialty scope of practice

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

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

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

level of regulation of their professional activities, largely due to the evidence base in relation to risk-associated with this area of practice.

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

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

3. Typical elements of professional certification models

Defining certification

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

The United States (US) 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; Ingvarson, 2014).

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 (PAI) 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.”

More relevant to the medical laboratory scientists 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 (ABNS):

"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 pre-determined standards.

A number of critical features or elements must be considered in the final design of a certification system that will contribute to objectives such as quality and safety in the context of the profession.

Features of a certification system

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

Participation requirement

Certification systems are overwhelmingly voluntary (Chanduvi, 2011; Gourley et al., 1997; Ingvarson, 2014; Knapp, 2000); in other words, participation by individuals in the scheme is voluntary and in general there is no requirement for certification to be undertaken. Few agencies, such as the US National Occupational Therapy Credentials Board and the American Dietetic Association's Council on Dietetic Registration, have successfully lobbied for certification to be a legislative requirement for practice (Knapp, 2000).

Generally certification is seen as a complementary activity - a 'value-add' to the employability of an individual (Chanduvi et al., 2011). It has been acknowledged that voluntary certification, however, can become a requirement or the default position due to the perceived value for the individual, employing organisation or general public (Ayres, 2009; Culley et al., 2013; Perlstein et al., 2014).

The basis of competency assessment

Some certification schemes rely only on achievement of qualifications as a demonstration of suitable competence, and so the onus of certification effectively falls back on to the accreditation of courses, leaving the certification scheme only limited standing.

More often though certification systems require the development of standards to measure competence (Knapp, 2000). Generally these standards also become the benchmark for assessing suitable qualifications (that is the accreditation process). Competency standards 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).

Defining the standards to measure someone as 'competent' can be achieved through the development of a competency framework. A competency framework provides a model of the desired outcome by defining required competencies as well as how they should be assessed (ASRM, 2015), therefore structured and validated competency based curriculum and assessments are seen as a necessary tool for certification programs (Wang et al., 2011).

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

Cost of certification

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. Cost of certification has been cited as one of the most common barriers to achieving certification with some programs offering 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
- recertification fees are an important source of income
- development and administrative costs per candidate will be dependent on the complexity of assessment processes.

Entry requirements

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 programs (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 exclude qualified candidates (Knapp, 2000).

Methods of assessment

Assessment of competency is generally conducted through a combination of methods of assessment for the attainment of initial certification and recertification.

Assessments for initial certification, in addition to minimum entry requirements (see 'Entry requirements'), can include:

- examination (Gourley et al., 1997; Mackinnon et al., 2012), including online examination
- 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 (Chanduvi et al., 2011)
- portfolio that demonstrates evidence against performance standards or competencies (Ingvarson, 2017).

The method of assessment for certification, and particularly recertification, needs to be accepted and relevant to the profession and individuals (Termuhlen et al., 2016). Strategies for ensuring accessibility to assessments such as timing, location and method can influence rate of uptake of certification (Perlstein et al., 2014). Knapp (2000) argues, however, that where the volume of candidates exceeds 500 individuals, convenience and accessibility may need to be sacrificed for practicality and cost-effectiveness.

Recertification and maintenance of certification

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 should therefore be carefully considered and designed.

Accountability and governance

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 and then separate from the system once established. Alternatively, the certification system may be launched independently from the beginning with seed funding.

By-laws provide a road map of the organisation's purpose as well as how it will function and include details about board structures, composition, appointment and terms of office. Board members 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).

Sanctions

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.

Levels of certification

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 laboratory assistant, technician, scientist, senior scientist. But they can also relate to levels proficiency within a single profession such as ‘initial (or entry) level’, ‘managed’, ‘defined’, ‘predictable’ and ‘optimisation’ of the People Capability Maturity Model (Chanduvi et al., 2011).

Certification in Molecular Diagnostics in the US, for example, is offered by a number of organisations for one of three levels (Mackinnon, 2012):

- Medical doctor – licensed in the diagnosis, management and treatment of conditions
- Doctoral-level – apply genetics to medical care in several specialties and function as the director of a molecular diagnostics laboratory
- Supervisors and Technologists – responsible for the technical and scientific oversight of a laboratory performing high complexity testing, but do not fulfil requirements for laboratory director.

Chanduvi et al. (2011) similarly describe levels within the International Project Management Association (IPMA) certification system, defined according to function of competence:

- Level A: Director of Project Program
- Level B: Director of Projects
- Level C: Professional in the management of Projects
- Level D: Technician in the management of projects.

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.

4. Current Australian context of health profession quality assurance

Different quality assurance approaches

This section sets the scene for how Australian health professions are deemed competent to practice. In Australia (and overseas jurisdictions with similar health systems), the term “health profession” encompasses a very wide range of professional contributions to the process of health care service provision. “Health profession” is taken to include (but is not limited to) the following professional roles:

Medical practitioners, nurses, midwives, Aboriginal and Torres Strait Islander health practitioner, medical scientists, clinical scientists, physiotherapists, occupational therapists, dietitians, medical radiation practitioners, chiropractors, optometrists, psychologists, Chinese medicine practitioners, chiropodists/podiatrists, pharmacists, osteopaths, dental practitioners, social workers, exercise sports scientists, exercise physiologists, audiologists, sonographers, perfusionists, orthotists/prosthetists, speech pathologists, operation department practitioners, orthoptists, hearing aid dispensers, paramedics, arts therapists, oral health practitioners, nutritionists, emergency care technicians, genetic counsellors, medical physicists, naturopaths, public health practitioners, clinical myotherapists.

In addition to these professions, there is a further group of “assistant” type health professions, which includes (but is not limited to):

Laboratory technicians, physician assistants, enrolled nurses, phlebotomists, allied health assistants, dental assistants, basic ambulance assistants, ambulance emergency assistants, emergency care technicians, clinical associates, anaesthetic assistants, health assistants, laboratory assistants, opticians, medical radiation assistants.

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

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

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

Regulatory approach

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

Figure 2 Objectives of the NRAS

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

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

There are currently 14 regulated health professions in Australia, each governed by a profession-specific board. However, in addition to any specific requirements each board may set in relation to the competency of its individual profession, the NRAS scheme requires that all professions meet core requirements for the following standard topics:

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

In addition to these threshold requirements, each of the 14 regulated health professions is required to develop its own professional competency framework which defines the capabilities and outcomes expected of a qualified health practitioner in that specific field. The national dietitian competency framework that has been developed, implemented and refined over time for setting standards of practice by the Dietetics Association of Australia (and applied to its membership for the purpose of self-regulation) provides a good example of how such a framework can be effectively operationalised (see also Section 6 for further detail on this framework and its implementation).

According to the discussion paper released by the Council of Australian Governments Health Council (COAG)'s independent review of accreditation systems in February (AHMAC, 2017), each professional competency framework under the NRAS currently differs across its domains (or fields or elements) that define a competent health practitioner. This does not, however, mean that there are

no common themes between the professional standards sets. In a study undertaken by the Australian Learning and Teaching Council (ALTC, 2011) and designed to identify commonalities between the professions, a set of core Threshold Learning Outcomes were identified across the competencies that have been identified as relevant for Health, Medicine and Veterinary Science professional education and training.

Threshold Learning Outcomes for Health, Medicine and Veterinary Science

http://disciplinestandards.pbworks.com/w/file/52723773/altc_standards_HMVS_210611.pdf

Upon completion of their program of study, healthcare graduates at professional entry-level* will be able to:

1. Demonstrate professional behaviours
2. Assess individual and/or population health status and, where necessary, formulate, implement and monitor management plans in consultation with patients/clients/carers/animal owners/communities
3. Promote and optimise the health and welfare of individuals and/or populations
4. Retrieve, critically evaluate, and apply evidence in the performance of health-related activities
5. Deliver safe and effective collaborative healthcare
6. Reflect on current skills, knowledge and attitudes, and plan ongoing personal and professional development.

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

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

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

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

Self-regulation approach

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

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

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

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

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

Although this is not directly relevant to the current certification project, it may be interesting to note that, in its draft findings review report (AHMAC, 2017), the review team proposes amendment of the NRAS to allow unregistered health and social care professions to apply to access the skills and expertise of the Accreditation Board and operate their accreditation activities under the umbrella of the Accreditation Board, subject to specified conditions and in a manner that would have no implications for the registration of those professions. All applications for registration would continue to be dealt with through established Ministerial Council processes and in accordance with the COAG Health Council agreed criteria.

Current pathology laboratory quality assurance approach

In 1986, the Commonwealth introduced a compulsory accreditation system in relation to Medicare benefits for pathology. In order to be accredited, pathology laboratories must meet the specified quality standards in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017*. This in effect results in virtually 100% participation by laboratories in the accreditation arrangements. NATA is the current independent assessing body for medical pathology laboratories.

In addition to the voluntary professional development and recognition options outlined in the sections above, the national laboratory accreditation assessment scheme (which incorporates both professional auditors and peer assessors) includes consideration of the competency of staff in each laboratory. This does not include an assessment of competence of each individual member of staff, but rather an overall assessment of the systems laboratories put in place to assure the likelihood of each and every staff member being competent. Such systems rely on qualification checks, review of test errors, training structures and arrangements, professional association membership, etc.

5. Selected certification case studies

Australian health profession certification schemes

Dietitians

Scope

Although they are not a registered profession under the AHPRA regulatory scheme, Dietitians Association of Australia (DAA) were a founding member of the NASRHP coalition, and their processes appear to largely conform to the “ideal” approach to recognition of health professionals as outlined in the NRAS. In many senses, the Accredited Practising Dietitian (APD) program mimics the approach and effect of registration.

This is probably a consequence of the history of the program, in that it was initially a response to the removal of registration requirements for dietitians in Victoria in the early 1990s. The DAA at the time determined that some form of individual certification was still warranted, and so in 1994 the current scheme, in a slightly less sophisticated form, was implemented.

The scope of the program is dietitians who have qualified through a DAA accredited course in Australia, or a course overseas which has mutual recognition. Overseas graduates from a non-recognised institution must obtain Dietetic Skills Recognition (DSR), which involves a combination of desktop analysis of qualifications, an examination and counselling. For persons with the above but not current practice for the last 3 years, alternative pathways into the APD are prescribed on application, which usually involves a period (12 months) of supervised practice.

Governance and accountability

The APD credentialing program for dietitians is managed by DAA. The APD program is governed by the Dietetic Credentialing Council (DCC), an independent council of the DAA Board.

The DCC’s primary function is to provide strategic advice and make recommendations on credentialing and regulation to the DAA Board on the APD program. The DCC is guided by, and adheres to, the Standards set by the National Alliance of Self-Regulating Health Professions (NASRHP). The role of the DCC in more detail is:

- To provide strategic advice to the DAA Board on the development of standards, codes and guidance guidelines for the APD program for the DAA as a self-regulated profession
- To provide high level advice to the Board about the development of the credentials within the APD program, that is Provisional, Full, Advanced and Fellow APD
- To ensure that the APD program meets the needs of the DAA, members and other key stakeholders, including consumers, with respect to safety and quality
- To liaise closely with the Australian Dietetic Council (ADC) regarding issues underpinning competency standards, credentialing, regulation, education, accreditation and recognition activities.

There is no direct government support for the APD. However, it was noted by program implementers that the Australian Government appreciates the APD, and regularly cites its existence as a tick mark for the profession.

Competency basis

The Dietitians Association of Australia have a long-standing set of competencies (regularly reviewed) that guide a) the accreditation of relevant university courses, b) professional practice and mentoring, c) CPD, and d) assessment of overseas-trained dietitians.

The National Competency Standards (NCS) for Entry-Level Dietitians in Australia was originally published in 1993 and has been reviewed in 1998, 2005 and 2009. The most recent national review of the NCS took place in 2014 and a consultative process was carried out in 2015 to plan for the transition of the revised standards into practice. The latest version of the NCS better aligns to other health professional competency standards, with an emphasis on the professional attributes required for dietitians to work across multiple contexts in the increasingly complex health system. It consists of four competency domains:

- Domain 1. Practices professionally
- Domain 2. Positively influences the health of individuals, groups and/or populations to achieve nutrition outcomes
- Domain 3. Applies critical thinking and integrates evidence into practice
- Domain 4. Collaborates with clients and stakeholders

Each domain has two or more competencies, there being 14 competencies in total. The next revision of the NCS will be completed by 2021.

Participation requirement

Participation is voluntary, however, participation in the APD program is strongly promoted. The APD register is also promoted to consumers as a way of identifying quality providers.

Currently there are 5,678 APDs. DAA estimates this is approximately 95% of dietitians the Association know about, which translates into an estimated 80% of the eligible workforce. This extremely high penetration is explained by the duration of the program (over 20 years) and the great benefit participants find in being certified. Observers indicated this was as much an intrinsic as extrinsic incentive for participants, bound up in the professional branding and pride in APD membership. Of course, there is potential direct value to individual dietitians (and particularly for those in the private sector) as a marketing tool including a register to which prospective customers and/or employers can go for assured services.

As APD is the only credential for dietitians recognised by the Australian Government for Medicare and Department of Veterans' Affairs (DVA) funding purposes, there is another strong financial incentive to participate. This is reinforced by recognition of the APD by many state governments and many private health insurers.

Levels of certification

The APD program has three credentials:

- APD
- Advanced APD (AdvAPD)
- Fellow.

AdvAPDs are professional leaders in their field of nutrition and dietetics, with high level knowledge and skills demonstrated in five domains of practice. These are Leadership and Influence, Professional Competence, Research and Evaluation, Education, Supervision and Mentoring, and Strategic and Reflective Approach to Practice. Professionals operating beyond the standard dietician scope of practice are generally recognised as AdvAPDs.

Entry requirements

The base entry requirement is to have completed an accredited course or obtained DSR, and be currently practicing in the workforce. Membership of DAA is not mandatory, and indeed there are some APDs who are not concurrent members of DAA. However, *eligibility* for membership is required.

Assessment

To attain and maintain APD status a dietitian must meet the Standards required of the program. The program requires dietitians to:

- undertake an initial year in the Provisional Program. This involves completion of the required CPD, and having the formalised support of a full status APD mentor for at least 52 weeks
- all APDs (both provisional and full) must log a minimum of 30 hours per calendar year of CPD activities.

Duration of certification

All APDs must be able to declare 'Recency of Practice' indicating they have practised as a dietitian and to the timeframe as required by the Standards and as per requirements set by the DAA Board. This in effect means that any absence from the workforce for 3 years can require evidence of current competence, and any absence of greater than 5 years effectively requires individuals to begin the participation process from the beginning.

Sanctions

APDs demonstrate their commitment to ongoing education and are committed to the Code of Professional Conduct and Statement of Ethical Practice. A small but significant (5%) of APDs are subject to annual random audit, and individuals who fail the audit can be subject to disciplinary actions (for example 12-month suspension, or to demote status to provisional and require recertification in 12 months). APDs can be subject to consumer complaints and a disciplinary process if required.

Observers noted that the disciplinary process was very important since there are always some people who operate outside of the parameters and they destroy credibility of whole scheme if not isolated and treated appropriately.

While the process of sanctions is not meant to be punitive but rather supportive, through the use of mentors etc., it is an important tool in maintaining system credibility.

Cost of certification

The individual contribution is \$642 per annum for a full-time practitioner. For members of DAA the fee is \$708 per annum but this provides additional membership benefits. The scheme is claimed to be self-sustaining based on the current fee structure and it was indicated that it could still run

effectively on much lower participation numbers but with possibly less sophisticated elements. The scheme is said to be supported by a complex database, which adds significantly to costs.

In total the APD was estimated to run off a budget of close to \$1.5 million annually which includes all infrastructure costs.

Exercise scientists and physiologists

Scope

The exercise scientist workforce consists of many categories of worker that can lay claim to the title. The relevant peak professional body, Exercise and Sports Science Australian (ESSA), has attempted to bring order and consistency to the industry workforce through accreditation⁵ (of education providers and individual professionals). ESSA claims over 6000 members made up of:

- Exercise Scientists – who use exercise to improve health, wellbeing and fitness
- Exercise Physiologists – who use exercise to help manage chronic conditions and injuries
- Sports Scientists – who use exercise to improve sporting performance
- High Performance Managers – who manage a range of performance services for elite sport

ESSA is a committed member of the NASRHP. It identifies a number of benefits of membership including:

- strengthens ESSA and ESSA professionals' commitment to consumers to practice safely, effectively and to a high standard
- strengthen ESSA and accredited professionals' position and recognition within the Australian health care system
- extending the NASRHP standards across all ESSA professions promotes recognition of the quality and excellence of all ESSA professionals

Governance and accountability

The credentialing schemes are all administered by ESSA. The setting of standards, though, is managed through a number of separate governance arrangements that include independent members. These include:

- ESSA Exercise Science Advisory Committee
- ESSA Exercise Physiology Accreditation Review Committee
- ESSA Sports Science Accreditation Advisory Committee.

Levels of certification

There are four separate credential levels as follows:

- Accredited Exercise Scientists (AES)
- Accredited Exercise Physiologists (AEP)
- Accredited Sports Scientists (ASpS)

⁵ ESSA uses the term 'accreditation' in all contexts, but in regard to the accreditation of professionals the process is essentially what elsewhere in this Discussion Paper has been defined as 'certification'.

- Accredited High Performance Managers (AHPM)

The base credential is AES, which requires the attainment of an appropriate 3-year degree before seeking the AES credential. The following three credentials effectively require demonstrated competence at the AES level before being allowed to participate in the higher level credentialing program.

Competency basis

Each of the credentials are underpinned by a separate set of professional competency standards made up of between 5 to 14 units of competence. These standards set the requirements for both individual competence and 'accredited' course requirements. They are not intended to limit the scope of practice, but instead represent a basic structure.

By way of example, the AEP Professional Standards meet the Australian Qualification Framework (AQF) requirements at Level 7 that lead to four-year Bachelor Degree qualifications. The AEP Standards are organised into 13 study areas, with Generic Standards 1 to 5 broadly describing practice of the profession. Standards 6 to 13 (pathology-specific domains) describe sets of knowledge and competencies that are needed to provide safe and effective exercise services for various broad-based pathology domains. This includes the capacity to practice across multiple pathology domains in a single client (i.e. co-morbidities and complex conditions). This structure recognises that learning and competence is built cumulatively through application of the broad practice Standards (Standards 1 to 5) and then applied to clientele typically seen by AEPs (Standards 6- 13 pathology-specific domains). This provides AEPs with the breadth of knowledge and skills to prescribe exercise for clients presenting with complex and / or chronic conditions, and managing multi-pathology relationships and priorities.

Participation requirement

There is a hierarchy of credentialing requirements based on the levels of credentials noted earlier.

The Accredited Exercise Scientist Professional Standards meet the AQF requirements at Level 7 leading to a *three-year* Bachelor Degree Qualification. AES participants in addition to completing a relevant course must also be able to satisfy the ESSA Exercise Science (ES) Standards, including 140 hours of practical experience.

An AEP holds a four-year equivalent university degree from an accredited institution and specialises in the exercise and movement for the prevention and management of chronic diseases and injuries.

To be credentialed as an Accredited Sports Scientist in Australia, an applicant must first substantiate that they have met the ESSA Accredited Sports Scientist Professional Standards (these are workplace based competency standards) and the prerequisite ESSA Exercise Science Standards. In addition they need to provide demonstrated evidence of 360 supervised hours of sports science professional experience. Suitable supervisors and assessors for different levels of Sports Scientist credential are listed in the guidelines.

An incentive for exercise physiologists to participate in the scheme is that AEPs are recognised in Australia as allied health professionals and are entitled to seek a Medicare Provider number. A similar entitlement to third party payments is afforded by the Department of Veterans Affairs.

Assessment

Assessment is largely undertaken for the AES and AEP through the accredited course provider and then through on-the-job supervisors. The sports scientist credentials require higher level supervision.

To support the supervision and ensure sufficient objectivity ESSA provide a number of templates and examples of Supervisor Forms, Logbooks and Practicum Guides.

ESSA may accredit people with an appropriate qualification and who also meet the Exercise Science Standards and /or AEP Professional Standards as an AEP.

Cost of credentials

AES - \$323.00

AEP - \$581.00

ASpS (all levels) - \$236.00

Genetic counsellors

Scope

Genetic counselling is a communication process that aims to help individuals, couples and families understand and adapt to the medical, psychological, familial and reproductive implications of the genetic contribution to specific health conditions. The goal is to facilitate the clients' ability to use genetic information in a way that minimises psychological distress and increases personal control.

Genetic counsellors are allied health professionals who work in partnership with clinical geneticists or other medical specialists. They can come from a range of professional backgrounds.

Certification is offered through the Human Genetics Society of Australasia (HGSA) and covers Australia and New Zealand. Since 1993 genetic counsellors have begun to formally organise their own affairs somewhat independently but still within the structure of the HGSA. The Australasian Society of Genetic Counsellors (ASGC) is a Special Interest Group (SIG) of the HGSA and has had representation on the HGSA Council. The ASGC had its own code of ethics ratified and published by the HGSA.

There are currently over 300 members of ASGC, all of whom are certified or in training to be certified. The 'flow' though into the certification scheme is limited by graduations from appropriate genetic counselling courses to a maximum of less than 20 per year.

Governance and accountability

The certification scheme was initiated and remains managed by HGSA since 1989. Under the HGSA the scheme is governed by a Board of Censors for Genetic Counselling. The current Board is primarily comprised of Certified Genetic Counsellors at least 2 years post-certification, and one member is a clinical geneticist, preferably at least 2 years post-certification. The chair is appointed from the Board membership. Board membership is for an initial three-year term, but can be extended for a second term by mutual agreement.

In 2008, the Board, together with the ASGC, and with the approval of the HGSA Council, established an Oversight Committee to review the process of certification in genetic counselling and to substantially revise the training guidelines document. Membership of the Oversight Committee includes current Board members, members of the ASGC Executive, two convenors of Australian postgraduate genetic counselling programs, and others to ensure a broad skill base and representation of all interests.

There is limited Government support for the certification scheme but it is recognised by most if not all public sector employers, and considered 'mandatory' for job applicants (at least Board eligibility, see below). HGSA is currently looking to becoming a recognised self-regulatory body by joining NASRHP and satisfying all of their requirements. This might allow a more aggressive promotion of certification to consumers.

Competency basis

The Oversight Committee developed a broad set of skills and competencies which informed the development of the assessment tasks. Candidates must complete these assessment tasks satisfactorily to attain HGSA certification in genetic counselling. The vocationally centred competency standards include:

- Competency Standard A: Communication skills - establishes and maintains a relationship with clients through effective communication, which promotes autonomy
- Competency Standard B: Reflective practice, counselling and interview skills - takes a self-aware, client-centred approach to facilitate client support and decision making
- Competency Standard C: Critical thinking skills - identifies, synthesises and organises pertinent information for use in genetic counselling
- Competency Standard D: Case management skills - facilitates best practice by advocating for clients, referring clients to appropriate services and maintaining comprehensive records
- Competency Standard E: Professional and ethical practice - promotes knowledge and access to genetic services through effective communication and education, maintains professional behaviour and boundaries in keeping with accepted codes of ethical practice, and promotes evidence-based practice for one's self and others through continual professional development.

These competencies inform the design and 'accreditation' of the Master of Genetic Counselling programs in Australia. The competencies also inform the development of the portfolio tasks and are the basis of the assessment criteria for these tasks.

Participation requirement

Participation is voluntary, however, seeking employment without at least provisional (associate) certification status would be difficult.

To participate in the certification program requires financial membership of the HGSA and to have completed a two year clinical Masters in Genetic Counselling qualification from a program accredited by the Board. In addition, the candidate must be employed a minimum of 0.4 full-time

equivalent (FTE) in a genetic counselling role, in a clinical genetics service that can meet the requirements for genetic counselling training.

Being eligible to seek certification allows a candidate to use the title Associate Genetic Counsellor and use the letters MHGSA after their name. Following certification, the scheme participant can use the term Genetic Counsellor.

The process of certification is effectively completion of an on-the-job training program during which there are a [comprehensive] series of assessments against the competency framework. The training can take anywhere between 3 and 4 years, depending on the capacity of the participant to master competencies.

Levels of certification

The HGSA grants certification via two successive stages:

- Board Eligible to Undertake Certification (**Associate Genetic Counsellor**) — this requires completion of a two year clinical Masters in Genetic Counselling or an equivalent qualification and a minimum level of employment in a clinical genetic counselling role
- Certification (**Genetic Counsellor**) — to progress to a ‘full’ Genetic Counsellor requires employment in a clinical genetic counselling role and satisfactory completion of a prescribed body of work related to clinical practice.

Assessment

The certification training goes through a number of stages, the end of each stage being marked by a “Portfolio Submission” that attempts to demonstrate a certification participant’s experience in relation to the competency standards. Each portfolio submission can include one or more of the following:

- Logbook - Candidates are expected to maintain a complete workbook of all cases they have been involved in while undertaking their certification, and draw from these cases for the logbook. The objective of the logbook is to demonstrate a breadth of clinical experience with respect to genetics, psychosocial issues and counselling skills. Cases selected should reflect specific clinical encounters.
- Long cases - The candidate is required to submit five long cases that are a maximum of 4,000 words each. Each case study is required to demonstrate the candidate’s knowledge, skills and attitudes within a specific area. Reflective practice must be demonstrated with each case study.
- Literature review or publication - The candidate is required to submit either a literature review on a topic directly related to the practice of genetic counselling, or a paper that has been accepted for publication in a peer-reviewed journal.
- Reflective skills assessments (transcript analyses) - Candidates are required to submit a reflective essay of 2000 words describing an audio or video-recorded consultation conducted as part of their standard case load.
- Candidate interview - The candidate will be required to undertake a face-to-face interview with two or three Board members.

- Supervisors' reports - Candidates are required to submit annual supervision reports from each of the candidate's supervisors, regardless of whether other assessment tasks are being submitted or not.

Supervision is an important and integral part of genetic counselling certification training. Supervision encompasses educational and supportive functions, development of self-awareness in the certification candidate, and may encompass case management functions. Supervisors (there are at least two but may be more) provide reports which are submitted annually.

Duration of certification

HGSA has adopted a "... maintenance of professional standards" (MOPS) program as a mechanism for assessing and maintaining the required knowledge and skills of its certified practitioners, and for ensuring client safety. Within the program, genetic counsellors can undertake self-directed learning activities that may be specific to their practice. MOPS submissions are required every five years. A MOPS submission must consist of:

- continuing education report
- referee reports from genetics and counselling supervisors for those working in a clinical role, including frequency and type of supervision.

Certified professionals must have (1) worked as a Genetic Counsellor or made a contribution that is of direct relevance to the practice of genetic counselling (e.g. clinical, education or research) for a minimum of 1500 hours (approximately 40 weeks' FTE) in the previous five years (2) participated in a minimum of one hour per month of genetic counselling supervision if working in a clinical role and (3) completed a minimum of 125 hours (i.e. 25 hours per year) of learning activity relevant to the area of practice.

Cost of certification

The fee for applying for Board Eligible Status is AU\$150.

The fee for applying for Certification is AU\$400.

The fee for MOPS is AU\$50.

Informants indicated that the current fees were too low and consequently placed a significant burden on volunteer [HSGA member] labour to ensure the scheme was sustained. Any efforts to raise fees in the past though had been met with resistance.

Health Informaticians

Scope

The health information workforce is an interesting case study since the 'profession' is comprised of individuals from many different backgrounds with quite varied skill sets. This includes clinicians who have determined to focus on health information concerns, through to clinical coders who make information accessible and the data accurate, to business analysts and information and communication technologists who have specialised in health data and the health industry. The scope therefore is very wide both geographically (Australia and New Zealand) and professionally.

Governance and accountability

The certification scheme, Certified Health Informatician Australasia (CHIA), has been developed by the Health Informatics Society of Australia (HISA), the Health Information Management Association of Australia (HIMAA), and the Australasian College of Health Informatics (ACHI) to address the lack of formal recognition of health informatics knowledge and skills in Australia. These are the three largest and most influential stakeholders in the health informatics industry within Australasia. There is no government involvement.

CHIA is accountable to only a limited extent to an internationally recognised set of standards and the need to retain consistency with other like professional bodies such as the American Medical Informatics Association and the International Medical Informatics Association.

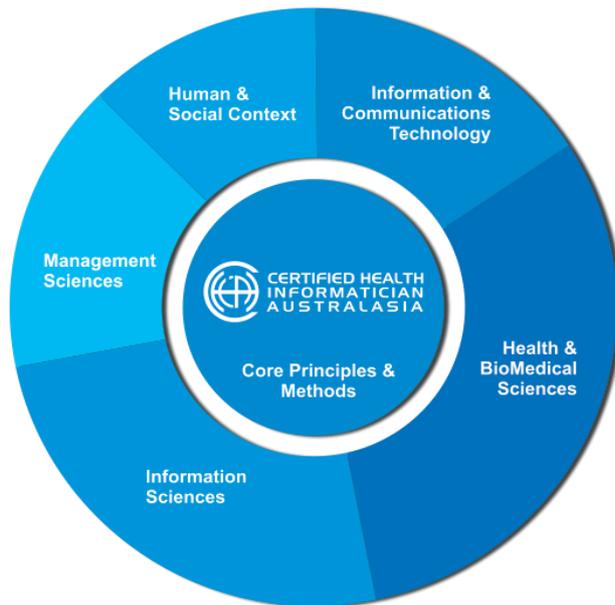


Figure 3: CHIA competency framework

Competency basis

CHIA was developed in line with global initiatives and competency standards from Canada’s Health Informatics Association (COACH). The competency framework identifies five main areas of work opportunity and competence (COACH, 2009) core to health information practice. The CHIA competency framework was further developed by Australasian academic leaders in the health informatics field (see Figure 3), following extensive research and review of other health and biomedical informatics competencies from across the globe.

The CHIA competency framework was designed with a focus on the Australian Healthcare system and is the backbone to Australia’s industry certification for health informaticians. It has five main areas of practice and additional ‘core principles’. Within each of these areas of practice there are a number of competencies totalling 52 in all.

Participation requirement

Choosing CHIA certification is entirely voluntary. Participation is almost entirely based on intrinsic incentives such as those promoted by the Scheme:

- being able to benchmark skills and competencies against others in a rapidly evolving digital health workplace
- use the CHIA credentials
- add value to personal career development
- be a change agent in the transformation of healthcare

The CHIA website promotes certification as a way of “... raising the profile of health informaticians, contributing to a wider recognition of the health informatics profession, and defining more clearly the body of knowledge underpinning this discipline” and promise:

“... with healthcare and computer science professionals topping the skills shortages list in Australia, CHIA certification is an exclusive and unique industry professional certification that will help you to stand out from the crowd and be part of a growing network of certified health informaticians in Australia.”

Currently there are 330 certified practitioners. Sources indicate that this is still only a fraction of the potential certified ‘market’, with close to 10,000 nurses alone operating in clinical informatics type roles in Australia and who could benefit from certification of their informatics competencies. Even so the numbers have been boosted in recent times by the use of the CHIA certification as a de facto training process by the NSW and QLD health authorities, and insisting on their relevant workforce completing the certification, for which training is frequently required.

Entry requirements

In order to register and sit for CHIA recognition eligibility requirements must be satisfied including a degree (any degree and does not have to be in health informatics) plus three (3) years of associated experience in health informatics.

Assessment

Assessment is through an entirely online examination based on all 52 health informatics competencies in the CHIA Framework. After registering for assessment, prospective Scheme participants have 90 days from the date they receive learning materials and instructions (usually the first Friday after registration) to log in and sit the exam. Candidates can sit the exam a 2nd time within the first 90 days if they are unsuccessful at the first sitting.

As the exam is delivered online, candidates are notified of their result immediately following exam completion, including the scores achieved in each of the seven competency domains. This information can be used to help focus their study efforts for a second sitting of the exam if required. The exam:

- consists of 104 multiple choice questions – 2 questions on each competency at various levels of difficulty
- duration is 2.5 hours maximum

Exam questions are randomly generated from a bank of questions in each competency domain (i.e. students re-sitting the exam will not be given the same questions as the first time they sat the exam), and the whole examination process is managed by an Examination Committee comprising senior Australasian health informaticians. The current first-time pass rate for those sitting the online exam is between 60% and 70%. For some a second attempt still finds them short of competence. A Scheme observer noted that this could be because of the required breadth of health information knowledge required – some candidates while possessing great depth of knowledge in a specific area struggle to obtain the broader competency set.

In recent times there has been some critique of the online assessment process and a slightly more detailed process is likely to evolve that retains the online exam but adds further challenges. This is partly to overcome the continued use of the certification as a driver for training when the Scheme architects would like to see workers approaching the certification after having completed a relevant structured training program.

Duration of certification

Maintaining currency of health informatics knowledge, skills and experience is as important as gaining it in the first place. Accordingly, the CHIA credential is for a three-year period only after which it must be renewed or it lapses. During this time, participants are required to undertake a minimum amount of CPD activities in health informatics to maintain certification. To maintain and be eligible to renew the CHIA credential, participants must:

- earn 60 CPD points during your 3-year recertification cycle by participating in professional education activities
- maintain a record of CPD activity and points
- report CPD points to the CHIA Program Officer (upon receiving a request for renewal) and ensure your recertification fee is paid before your expiration date.

Re-certification is also possible in lieu gaining sufficient CPS points by resitting the online exam.

Cost of certification

Cost of certification to members (HISA, HIMAA, ACHI) is \$395 and slightly more expensive for non-members (\$520).

Recertification (if sitting the examination) costs \$100.

Overseas case study examples

Relevant US schemes

Scope

Although there is no overall competency requirement for medical laboratory scientists or technicians in the USA, the regulatory requirements by the US federal government to govern eligibility of laboratories to undertake pathology testing under the Medicare and Medicaid funding arrangements operate as a default national framework that governs this workforce.

The Clinical Laboratory Improvement Amendments (CLIA) requirements also reference state licensing requirements for laboratory personnel. Practising licences are required in 13 US states and territories - California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Tennessee, West Virginia and Puerto Rico. Until it deregulated approximately 30 professions in July 2016, Rhode Island also required licensing. These individual jurisdictions apply varying requirements in terms of entry-level education and training course completion, on-the-job training, certification and CPD. In some cases, licensing is granted on the basis of certification. A summary of these requirements can be found at - <http://www.ascls.org/advocacy-issues/licensure>

Governance and accountability

Certification is offered by a number of ‘accredited’ agencies, but the Board of Certification founded by the American Society for Clinical Pathology (ASCP) in 1928 is widely accepted as the most influential leader in the field of certification of medical laboratory professionals. To date over 500,000 individuals have been certified. The Board of Governors of the ASCP Board of Certification has 24 members including:

- pathologists (nominated by the ASCP)
- laboratory professionals (nominated by the ASCP)
- representatives from the American Society for Clinical Laboratory Science (ASCLS)
- representatives from the Association of Genetic Technologists (AGT)
- at least one representative from additional participating specialty societies.

The American Medical Technologists (AMT) professional organisation also offers a widely used certification service which has similar requirements and covers a similar range of profession types. Their website provides the following description of the aim of their scheme:

“Certification represents your declaration of professional competence, both current and ongoing. This declaration is for your benefit, as well as for your employer and for the public-at-large.”

Competency basis

The relevant laboratory accreditation framework operates under the Clinical Laboratory Improvement Amendments statute of 1988 (CLIA ‘88) under the US Public Health Services Act and is overseen by the Centers for Disease Control and Prevention. The CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. The accreditation framework is monitored by two key assessment agencies – the College of American Pathologists and the Joint Commission.

In 2012, more stringent requirements were introduced under the CLIA ‘88 framework whereby each member of staff in an accredited laboratory needs to be assessed in six competency domains by suitably qualified and experienced colleagues/supervisors in the laboratory each year (and twice in the first year of professional practice; CMS, 2012). Accrediting organisations, such as the Joint Commission, have also raised issues in this area. Malone (2017) noted that competency assessment was one of the most frequently cited areas for lack of compliance by the Associate Director of the Standards Interpretation Group at The Joint Commission, in an interview with the US professional organisation American Association for Clinical Chemistry. The Associate Director went on to note:

"In 2012, 39 percent of labs were cited for non-compliance. In many cases, we're seeing that not all six of the competency assessment criteria are being utilized, and the required frequency of six months during the first year and annual thereafter falls short in some laboratories. We've also noted that frequently the individual performing the competency assessment does not really have the required qualifications."

Laboratory directors and managers should also explain why competency assessment is important in the first place. Malone (2017) quoted an education coordinator from the Mayo Clinic:

"I think it's really important to explain to your staff that competency is not just a compliance issue. The goal is that we're doing quality work: we want to provide the highest quality test results that we can, and to do that we're doing quality checks on our staff ... Don't take it as something punitive—we do quality checks on the instruments, we do quality checks on the process, so we're going to do a quality check on you to make sure we're providing our patients with accurate test results."

The Associate Director echoed this idea.

"Too frequently managers feel that competency assessment is a snapshot in time, when you actually have a year to gather the data that's used to determine the competence of your staff ... It makes a lot more sense to gather that data as a continuum. The direct observation of testing, the monitoring of the recording, review of intermittent results, and so on, does not have to happen at one point. It happens on an ongoing basis, and most of it happens in the routine supervisory review process."

Although this competency testing is undertaken as part of laboratory accreditation-related activities, the mechanism of regular assessment of the competency of all laboratory staff within their scope of practice offers a potential source of input into a certification scheme.

While significant testing of capacity also occurs through certification examinations, it is not clear that the exam questions are designed in relation to a set of competency standards.

Participation requirement

It is not compulsory for members of the medical laboratory workforce to hold a relevant certification. However, a number of the state licensing schemes require participation in a certification program and it appears to be the case that certification is increasingly sought by employers. For example, the US Navy includes certification as one of its entry requirements their laboratory professional staff.

The CLIA Personnel Requirements for Testing Personnel (i.e. core scientific workforce) (<http://www.aafp.org/practice-management/regulatory/clia/personnel.html>) prescribe a wide range of possible qualification and training options, leaving employers wide discretion as to who is employed for these roles.

Levels of certification

US certification schemes tend to be highly inclusive of levels of competence (technician, scientist/technologist, specialist pathologists) and areas of laboratory practice. For instance, the ASCP certification scheme offers particular options for the following areas of practice:

- Phlebotomy
- Medical Laboratory Scientist
- Cytotechnology
- Histotechnology
- Blood Banking
- Cytogenetics
- Haematology
- Microbiology

- Molecular Biology.

Assessment

The certification process from most certifying bodies seems to consist mostly of two stages.

- Step 1 is to meet the eligibility requirements for the appropriate examination category, which generally implies having completed a requisite course of study. In lieu of having completed an ‘accredited’ program, alternative course pathways are accepted, but with demonstrated levels of practice in relevant workplaces and with relevant experience.
- Step 2 is to take an online examination at a third-party organisation (presumably to ensure the right person is completing the examination).

The ASCP Board of Certification uses computer adaptive testing (CAT) for its online examination, which is criteria referenced. This means that an examinee’s score on the exam is not influenced by the scores of other examinees who take the exam. With CAT, when a person answers a question correctly, the next test question has a slightly higher level of difficulty. The difficulty level of the questions presented to the examinee continues to increase until a question is answered incorrectly. Then a slightly easier question is presented. In this way, the test is tailored to the individual’s ability level. The weight (value) given to each question is determined by the level of difficulty. Therefore, the examinee must answer enough difficult questions to achieve a score above the pass point. The examinations are mostly scheduled for 2 hours and 30 minutes with 100 questions.

Cost

The ASCP certification scheme offers certification across many different categories ranging from US \$135 to \$530.

United Kingdom

Scope

‘Biomedical’ and ‘clinical’ scientists are two of 16 health professions registered in the United Kingdom through the Health and Care Professions Council (HCPC)⁶. All who want to work in the medical / clinical science profession in the UK must be registered. The following specialist areas are included in clinical science:

- Clinical Biochemistry
- Clinical Genetics
- Clinical Immunology
- Clinical Microbiology
- Clinical Physiology
- Embryology
- Haematology
- Histocompatibility & Immuno-genetics.

Currently there are approximately 23,000 biomedical and 5,500 clinical science registrants in the UK.

Governance and accountability

⁶ Doctors and nurses are registered through separate bodies.

The HCPC is similar in function to AHPRA in Australia and was set up to protect the public. To do this, it keeps a register of health and care professionals who meet the designated standards for their training, professional skills, behaviour and health. The HCPC publishes the relevant set of standards of proficiency which guide the core requirements of training and education, entry to the profession and the basis for CPD that enables ongoing recognition of professional competence.

The standards of proficiency for Biomedical Scientists are prepared by the Institute of Biomedical Science (IBMS) and certification against these standards is also administered by the IBMS.

Competency basis

Proficiency is established via a combination of approved course qualifications and the acceptable completion of a Training Portfolio in an approved training laboratory which requires a series of Performance Criteria to be assessed by an approved Trainer in the training laboratory. The duration of on-the-job experience required will depend on the academic qualifications achieved, and may vary from 3 to 6 years.

The professional requirements for medical laboratory scientists in the UK are prescribed by the HCPC under the national registration standards for Biomedical Scientists and Clinical Scientists.

The HCPC standards of proficiency for registrants include both common and profession-specific elements. Its standards of education and training are common across professions and cover the level of qualification, program admissions, program management and resources, curriculum, practice placements and assessment. Benefits of the model are demonstrated in such areas as consistent expectations for inter-professional education, consumers and care involvement, etc. The HCPC also provides a single and consistent approach to accrediting education programs against those standards through its Education and Training Committee – which has been given statutory responsibility for approving and monitoring education programs.

For different routes individuals travel towards registration, all still require a portfolio of evidence of their experience. This total experience must then be confirmed by interview, in which an assessment of their portfolio of evidence of training and experience will also be required to confirm attainment of approved competences. The IBMS performs a quality control function for this portfolio submission process.

Levels of certification

Registration is only relevant to the science (degree-qualified) level of workforce. However, the IMBS also offers a Certificate of Achievement for laboratory support staff. This is not a mandatory requirement for work.

Cost

£180 per annum

South Africa

Scope

Similar to the UK, a range of allied health professions are required to be registered in order to practice. The governing body is the Health Professions Council of South Africa (HPCSA). Amongst the

professions required to register are medical technologists, within which the following groups are registered:

- 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

Governance

The Professional Board for Medical Technology, under the HPCSA, provides registration to eligible candidates. The Board is constituted by the HPCSA, and is established under legislation.

The Board registers individuals at three levels – Scientist / Technologist, technician, assistant. The requirements for technologists are obviously the more stringent and include the following steps:

- register as student medical technologists with the HPCSA
- complete a recognised three-year National Diploma in Biomedical Technology including experiential training completed at an accredited higher education institution and accredited training laboratory
- complete structured practical training (an internship) under the guidance and supervision of a suitably qualified medical technologist registered in that discipline for a minimum period of 12 months in full-time employment in an accredited training laboratory
- successfully pass an examination conducted by the Society of Medical Laboratory Technologists of South Africa on behalf of the Professional Board.

Assessment

The Society for Medical Laboratory Technologists of South Africa (SMLTSA) conducts examinations on behalf of the Professional Board for Medical Technology. The examination does not seem to be based on competencies.

Intern Medical Scientists (Medical Biological Scientists, Medical Physicists and Genetic Counsellors) though as noted above are required to submit a portfolio for assessment upon completion of twenty-four (24) months internship training. The portfolio should reflect all components of approved training program. For this component, a form of competency standards is provided, although it could be more seen as a checklist of areas of practice - that is, more like a job description list than a competency framework.

Cost

The cost for sitting the examination for a technologist is Rand 1,320 (\$AUD123). The annual registration fee is Rand 1,275 (\$AUD118).

Summary of case study examples

The seven case studies are compared in summary form in Table 3. It indicates that:

- The scope of certification can vary between covering a single profession through to covering a range of related professions or even occupations. The situation that pertains in medical science in Australia, with a number of highly related specialty professions, has been the model of several certification schemes.
- In a similar way, scope of certification schemes can cover a range of ‘vertically’ related occupations, where the link between the occupations / professions might be an extended career pathway.
- Governance arrangements tend to favour third party arrangements, where the establishment of the scheme principles, rules and procedures, if not as well the scheme implementation, is undertaken by an independent body. Direct government involvement was only identified in the case studies where the profession was registered, but indirect involvement (especially through recognition of the scheme that results in financial benefit) was clearly helpful.
- For most schemes participation is voluntary, with the focus on increasing participation levels through provision of demonstrated benefits.
- Nearly all the schemes are underpinned by a set of competency standards or a competency framework. The same framework often also underpins processes of course accreditation. Completion of such courses is almost invariably a prerequisite for entry to a certification program.
- Assessment methods vary significantly in nature and depth of competence examination, ranging from comparatively low cost online examinations to very intensive interview and written examination processes. Most certification schemes include an assessment of on-the-job experience / performance.
- Requirements for recertification and the imposition of sanctions when certified participants are non-compliant with scheme rules varies across schemes, and are the components that are more likely to be not included.

In Appendix A, the brief details of a total of 24 certification schemes identified and examined from Australia and several overseas countries are provided. It indicates that 58% (14 of 24 schemes) are based on some form of competency framework and that most have an associated lifelong learning program (for instance compulsory professional development program, or MOPS) which is based on the same competency framework. Annual cost of certification to the individual participant ranges from a low of \$130 per annum to as high as \$1,000

Table 2: Summary of case study certification scheme components

Scheme components	Dietitians	Exercise scientists	Genetic counsellors	Health informaticians	Medical scientists (USA)	Medical scientists (UK)	Medical scientists (SA)
Scope	Single profession	Several related professions	Single profession	Single profession	Several related professions	Several related professions	Several related professions
Governance arrangement	Independent Council set-up by DAA	ESSA plus Review Committees to establish competence standards	Independent Oversight Committee established by HGSA	Independent body created with three professional association share holders	Independent of professional associations	HCPC – similar to AHPRA	HPCSA – similar to AHPRA
Government involvement	None, but use of scheme to filter access to Medicare Benefits Scheme (MBS) items	None, but use of scheme to filter access to MBS	None	None	None, but required to access government health insurance programs	Support of registration	Support of registration
Participation requirement	Voluntary but high participation levels	Voluntary	Voluntary, but essential to achieve employment	Voluntary, with career incentives	Voluntary but employer incentives	Mandatory	Mandatory

Scheme components	Dietitians	Exercise scientists	Genetic counsellors	Health informaticians	Medical scientists (USA)	Medical scientists (UK)	Medical scientists (SA)
Competency basis	Competency standards, reviewed regularly	Linked competency framework	Competency standards	CHIA competency framework	List of tasks only	Common professional standards	Unclear
Levels of certification	3 vertical levels	4 levels both vertical & horizontal	2 vertical levels	One level	Multiple vertical & horizontal levels	Horizontal levels	Horizontal and vertical levels
Entry requirements	Completion of accredited course	Completion of accredited course	Appropriate employment	Completion of relevant course + 3 years on-the-job experience	Completion of accredited course	Completion of accredited course	Completion of accredited course
Recertification requirements	3 years	Unclear	Submissions every 5 years + MOPS	3 years + proof of ongoing CPD			
Assessment methods	Log Supervised practice	Supervised practice Log book Supervisor	Log Case presentation Literature	Online examination	Online examination	N/A	Internship Examination Portfolio of experience

Scheme components	Dietitians	Exercise scientists	Genetic counsellors	Health informaticians	Medical scientists (USA)	Medical scientists (UK)	Medical scientists (SA)
		reports	review Self-analysis interview Supervisor report				
Sanctions	Yes, 5% audit of participants annually Discipline for non-compliance		Yes, requirement to undertake supervised practice			Yes	Yes

6. Assessment – how could that work?

As has been demonstrated through the case study work in Section 6, most certification schemes require satisfying assessment criteria over and above completing relevant qualifications. Assessment means (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 ...”

The assessment methods available, and which have each been adopted by at least one of the case study schemes, are detailed in Table 4⁷. The merits of each method are briefly discussed. These assessment methods may be used in the initial certification process, in regard to the maintenance of professional standing, the achievement of mid or senior level professional recognition standing, re-entry to a profession after a period of absence, and/or processes for administering sanctions/reassessment actions associated with not being able to meet required standards.

The NRAS for regulated Australian health professions (described in Section 5 above) allows for the initiation of a range of assessment approaches, including participation in an internship process and/or examination (AHMAC, 2017). The report notes that:

“... a national approach to competency assessment of graduates has the potential to increase consistency of outcomes, create system-wide data to benchmark across education providers and their health programs, and deliver reliable, standardised information on graduate performance and quality.”

⁷ There is a wealth of experience and knowledge on assessment that can be borrowed from Australia's vocational education and training sector (e.g. Department of Education & Training, 2008). In this Discussion Paper the types of assessment methods canvassed has been limited to those used by one or more certification schemes.

Table 3 Certification assessment options

Assessment options		Cost (personal and scheme)	Benefits	Risks
1.	Allow access to certification after a minimum period of employment (e.g. one or two years of workplace experience with little or no formal structure to address competencies required)	Low (but may be restrictive for profession/ employer if waiting period is longer than time required to attain competencies)	Easy to administer; low cost; informal internship period assures some level of orientation to professional practice in a laboratory accredited to NPAAC standards	Variable basis upon which to determine minimum practice standards
2.	Supervisor’s report (e.g. against broad competency requirements or guidelines)	Low (may require some guidance to be provided to both the professional and the supervisor)	Formalises an existing process; may not be constrained by a time limit if requirements can be met	May be difficult to influence supervisor behaviour; likely variability in assessment processes and outcomes
3.	Preparation of a competency based portfolio and/or completed checklist of professional development activities upon commencement of employment (one or two year formal induction/ internship period)	Medium (requires sustained attention to attainment of competencies and specific resourcing from supervisory staff to assess and sign off on competency achievement)	Provides a structured entry-level program of skill development; assists employers to set and assess against clear standards for practice; raises awareness of core competencies and professional practice risks	Portfolio requirements may be too onerous; employers may not wish to be constrained by external requirements; medium cost to administer at a national level
4.	Reflective skill assessment/ self-assessment	Low to medium (assessment process needs to be designed and distributed; audit process required to assure the effectiveness of this approach)	Onus is on the professional to be well aware of professional practice requirements in order to conduct adequate self-assessment	Assessment process is not rigorous enough to assess more complex and potentially risk-associated competencies

Assessment options		Cost (personal and scheme)	Benefits	Risks
5.	Observation of actual or simulated professional practice	Medium (agreed standards for assessment must be set and audited; independent assessors may be required)	Assessment is relevant to professional area of practice and standards are clear; could be integrated into routine supervisory activities	Employers may not wish to be constrained by external requirements; independent assessors may be difficult to find/afford
6.	Entry-level examination (either post-graduation or after a one or two year period of employment – written, oral and/or online assessment process) (e.g. South Africa, Canada, US CLIA requirements,	Medium to high (requires additional study post-graduation; usually has fees associated; requires establishment and maintenance of an examination board or other mechanism for setting, marking and moderating the examination plus administration of arrangements to communicate with candidates before and after)	Creates an independent benchmark for professional entry; gives employers assurance of core professional knowledge; raises awareness of core competencies and professional practice risks	Examination requirement (cost and stress) may be a significant barrier to uptake of certification; more complex and expensive system to operate nationally and therefore more expensive for applicants
7.	Competency based workplace assessment (this approach is similar to the US CLIA 88 requirement introduced in 2014 for employers to assess the competency of	Medium (requires intensive engagement by both the professional and supervising staff but addresses a current NPAAC /accreditation assessment requirement for demonstration and documentation	Provides objective and transparent basis for achieving competency; removes barriers between role competencies (e.g. progression from technician to scientist level work without hard boundary)	Puts very high onus on employers (or creates need for highly resourced central agency) to assess competencies in a consistent way; higher onus on laboratory accreditation assessment process to ensure

Assessment options	Cost (personal and scheme)	Benefits	Risks
scientific laboratory staff across six domains each year ⁸)	of competency)		initial competency
8. Interview process	Medium to high (requires preparation by both the professional and interviewer/ assessor; if undertaken by an external assessor, fees may be involved; administrative systems may be required to support and monitor satisfactory completion)	Allows for more nuanced and personal approach to assessment; builds network of professional contacts outside the workplace and with more senior professionals	May be more difficult to consistently apply an agreed standard of assessment

⁸ In the United States, the Clinical Laboratory Improvement Act 1988 mandates that competency assessment be completed for all technical, supervisory, and testing personnel for each test that an individual is approved to perform and must include the following elements for each test evaluated:

- (i) direct observation of routine test performance;
- (ii) monitoring the recording and reporting of test results;
- (iii) review of intermediate test results, quality control (QC) records, proficiency testing results, and preventative maintenance records;
- (iv) direct observation of performance of instrument maintenance and function checks;
- (v) assessment of test performance through testing of previously analyzed specimens, blind samples, or external proficiency samples; and
- (vi) assessment of problem-solving skills.

An initial assessment is required within the first 6 months following the initial training period and annually thereafter.

7. Factors that could influence scheme success

The conditions for successful self-regulation, equally applicable to a certification system, may include (Priest, 1998):

- there are relatively few industry players
- the costs of exiting from the industry are high
- there is a history of effective cooperation
- expertise and resources for regulation are available in the industry
- non-compliant behaviour can be punished
- consumers value compliant behaviour
- fair and adequate dispute settlement mechanisms are in place
- some role is available for public participation or oversight.

Priest (1998) also suggests that self-regulation works best in the "shadow" of government action and that governments cannot entirely relinquish their responsibilities for oversight of the public's interests, where a government response may otherwise be required.

Healy (2014), in identifying the value difference between regulated and self-regulated professions, at the same time highlighted potential elements of certification schemes that are potentially most important. This included:

- " ... a crisis of trust in health and human service professions". Healy noted that a certification system imperative to engage in monitoring and correction of deviant behaviour was likely to be in conflict with the social imperatives for collegial cooperation, and therefore undermine the credibility (or perceived credibility) of any scheme.
- " ... growing recognition of the rights of consumers in shaping health and human services." In this respect Healy notes service users are demanding that service providers are accountable to them and not only, or even primarily, to their own professional bodies.
- " ... challenge ... to the nature of the professional contract between practitioners and those whom we serve." In this regard Healy draws a distinction between trust (integrity) and confidence (competence) and that the latter must be shaped by " ... achievement of foundational educational requirements and ongoing engagement with professional learning."

Knapp (2000) in offering advice on how to set up a certification scheme in effect also identified the key features to which attention must be given as follows:

1. Before developing credentialing programs, test the marketability and feasibility of the concepts and determine the value added to individuals and the industry
2. Credentials must be credible to be acknowledged by candidates, employers, the industry, and the public. Credibility rests on the quality of program development procedures and safeguards built into program policies and the governance structure
3. Pay attention to legal issues, such as antitrust, defensibility of assessment, due process, confidentiality, and privacy, as they relate to credentialing

4. Develop a business plan with marketing strategies because the costs for developing and operating a credentialing program and the fees paid for credentialing by individuals and companies are significant
5. Make sure staffing and volunteer resources are available and committed to program development.

Finally, from the literature, Ingvarson (2017) noted that essential to the success of a professional certification scheme was to ensure the validity, reliability and fairness of the procedures used. This provides in some respects a summary of all the preceding points by other authors.

From an analysis of the case study certification schemes some key elements appear to be:

- Providing scheme participants with a sense of professional pride and public recognition of the extent of workforce effort that lies behind the professional processes. If it can be negotiated, tangible economic benefits in terms of a market presence and access to third party payment structures could be very helpful.
- Providing various levels of government with confidence that problems will be negligible in the profession, and that if they do arise they will be largely dealt with internally. This will help the profession's status and afford a greater degree of influence over other areas of policy affecting the profession.
- Providing consumer protection and confidence in services. The same might be said for employers (as more direct 'consumers' for instance of a certification scheme with an associated register of certified practitioners).
- Overt commitment to agreed competencies – upon entry and over the course of professional life.

As some case study and stakeholder interview subjects have indicated, if a certification scheme is to be attempted it must be highly credible, in terms of its perceived integrity, its validity and reliability in terms of actually measuring competence, and the way it identifies and deals with non-compliant behaviour and deficiencies in competence.

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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	Accredited degree	World Occupational Therapy (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, CE)	Yes	Yes	No	\$338, including MOPS (CPD)
Lawyer	Accredited degree plus specified Practical Legal	Yes	Yes	No	\$868 or \$798

Profession	Point of entry	Competency based Framework (Y/N)	CPD – competency based (Y/N)	More than one level of certification (Y/N)	Annual fee
	Training against set requirements/competencies (now usually a 6 month graduate professional qualification - “Legal Workshop” - Level 8 AQF qual)				
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) <u>or</u> 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, approx. \$300 recertification fee
United Kingdom	See case study – Section 6	Yes	No	Yes	~\$300
South Africa	See case study – Section 6	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	See case study – Section 6	Yes	No	Yes	\$135 to \$530
Canada (differs by province)	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