Narrative review

A Review of the Current Medical Science Career Framework in Australia and Recommendations for the Future

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Australian pathology laboratories are governed by a pathologist registered by the Royal College of Pathologists, Australasia (RCPA) and accredited by the National Association of Testing Authorities (NATA). It would seem that neither body support professional registration through the Australian Health Practitioner Regulation Agency (AHPRA) but have funded an independent program of certification for medical scientists.

This program aims to provide solutions to many issues within the profession, but it is entirely voluntary in nature. This means that it will not have the ability to sanction misadventure and with no universal mechanism to recognize the professional status of laboratory staff. This review intends to look at the current framework and identify deficiencies while making suggestions to address the concerns.

A three-pronged approach would seem most beneficial with the first being a revision of the National Accreditation Advisory Council occupational definitions. Secondly, the Australian Institute of Medical Scientists (AIMS) should provide relevant education for supervisory staff and discipline- specific fellowship pathways for laboratory management and clinical scientists and finally, the certification program should be scrapped as it currently has only 314 certified scientists, less than 1% of the approximated workforce.

Replaced with an employer financed, blockchain based credentialing framework which would provide accurate workplace data, a secure opensource framework and legitimate oversight of the competency and education of practitioners. There is a chronic under-recognition and lack of ongoing development of medical laboratory scientists within the Australian healthcare community which considering the importance placed on the accuracy of results during the pandemic needs to be addressed.

Key words: Registration, blockchain, credentialing

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Introduction

The International Organization for Standardization (ISO) was founded in 1947 to promote conformity in worldwide standards.[1] It is a union of two earlier organizations: the International Federation of the National Standardizing Associations (ISA) and the United Nations Standards Coordinating Committee (UNSCC).

The ISA was established in New York in 1926 but was based in Switzerland and its standards were adopted by many European countries that used the metric system. However, the ISA ceased operations at the beginning of hostilities in Europe. In contrast, the UNSCC was adopted by those countries that used the imperial system such as America, Canada, and the United Kingdom. The UNSCC was established as a branch of the International Electrotechnical Commission (IEC) since 1944 to aid the reconstruction efforts following the Second World War.[1]

In 1987, the ISO published its first quality management systems standard, ISO 9001, which described the fundamental principles of quality management. This standard has become one of the most popular management tools used today. In 1999, the ISO published the *General requirements for the competence of testing and calibration laboratories* as document ISO/IEC 17025:1999, which is used to assess the competence of most laboratories. Finally in 2003, the first edition of ISO 15189 *Medical Laboratories – Requirements for quality and competence* was released which provides specific advice for pathology testing.[2] These documents have formed the basis for standardization of clinical laboratories worldwide; and have been adopted by all 162 of the ISO member nations including Australia, wherefrom the National Australian Testing Authority (NATA) was formed in 1947.

Initially established to ensure the standard of munitions produced in Australia, NATA eventually expanded to provide services for a third of all chemical and mechanical laboratories in Australia by the end of the 1970s and began accrediting medical facilities in 1983. In 1988, NATA signed a Memorandum of Understanding with the Commonwealth Government of Australia to provide accreditation services across Australia, which would allow accredited facilities to claim Medicare benefits. Today, any Pathology laboratory in Australia must be inspected biennially to ensure that they hold to the standard required in order to practice.[3]

The National Pathology Accreditation Advisory Council (NPAAC) is a government appointed body charged with ensuring that laboratory staff are "*appropriately qualified, competent and have a relevant scope of practice and accountable for the testing performed.*"[4] This is done through the *"Requirements for Medical Pathology Services"* and "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories."*[5,6] Within the scope of these documents, their importance is described as providing standards for good medical pathology practice. Describing the categories of pathology laboratories, roles of key staff, including, Pathologists, Clinical Scientists, Scientists and Technical Officers, and ensuring that all tests are supervised by competent persons who are working within their Scope of Practice.

The Australian Institute of Medical Scientists (AIMS) is considered the largest professional body representing medical scientists in Australia. It provides various services that adhere to the NATA and NPAAC requirements for Australian laboratories. Along with the Australian Association of Clinical Biochemists, it commissioned the National Certification for Medical Laboratory Scientists and Technicians using funding from the Australian Government's Quality use of Pathology program (QUPP).

All of these important bodies have significant roles in defining the pathology service in Australia. With the imminent implementation of the certification scheme, it would seem prudent to review these documents to assess their impact on the disciplines as a whole. Where possible, it

would be valuable to recommend improvements to ensure that the new framework is relevant and meaningful to the Pathology Medical service in the future.

Australian Pathology Occupational Definitions

Internationally, the medical science profession is controlled by a governmental registration body and a professional society. The former has legal authority to apply sanctions to practitioners, when and if required, while the latter acts as a credentialing body and ensures the highest level of professional practice through continuing professional development (CPD). In Australia, medical science is not recognized as a profession and laboratories are controlled by a registered Pathologist and industry accreditation.

NPAAC has provided the standards of practice for the pathology services within Australia since 1999 with the first edition of the "*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories*" revised and reprinted in 2018.[6] This document includes definitions of the roles and functions of a pathology laboratory, and guidelines to ensure legislative compliance. All laboratories must comply in order to receive compensation through the Medicare fund.

To this end NPAAC has defined four grades of pathology laboratory workers in Australia. These grades are based on education and experience and encompass the role description Technical Officer through to Clinical Scientist.

1) A Technical Officer is someone who has completed a 2-year certificate or diploma level qualification in the field of pathology. These qualifications match those required of a Medical Laboratory Technician which is a classification provided under the Australian and New Zealand Standard Classification of Occupations (ANZSCO) 311213.[7] The question arises as to why this level of practitioner carries two different titles; one assigned by the NPAAC, and the other by ANZSCO.

2) A Scientist requires:

a) a degree at Australian Qualifications Framework (AQF) level 7 (Bachelor) with subjects relevant to the field of pathology, as determined by the person responsible for the scientific management of the laboratory and/or person responsible for the clinical governance of the laboratory, awarded from a university in Australia; or

b) a degree at Australian Qualifications Framework level 7 (Bachelor) with subjects relevant to the field of pathology awarded by an overseas tertiary institution if the qualification is assessed as equivalent to a degree accredited by the Australian Institute of Medical Scientists (AIMS), according to their authority approved by Australian Education International via the National Office of Overseas Skills Recognition (AEI−NOOSR); or

c) An associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973.

In practice, however, there are only two pathways to employment as a medical scientist in clinical laboratories in Australia, as the third is historic. The first pathway suffers from the problems of relevance and responsibility. In the context of relevance, what subjects are considered relevant to pathology?

Any life science graduate could be considered to have the requisite background to fulfil this criterion. But they will not have any understanding of test validations, quality control metrics or proficiency testing requirements. The net is therefore cast very wide and lacks any appreciation of vocational training. The issue of responsibility lies with the person determining the relevance of degrees, which appears to lie with either the scientific or clinical lead of an individual laboratory. Critically, the second pathway includes an objective body (i.e., AIMS) assessing the relevance of degrees, with universal responsibility for that assessment; however, this independent assessment only has authority over foreign qualifications.

The requirements to work as a medical scientist in Australia have evolved since the

2007 edition of the NPAAC "Requirements For The Supervision Of Pathology Laboratories" when a medical scientist needed an Australian qualification "*that provides for direct entry or following examination to a professional class of membership of the AACB, AIMS, Australian Society of Microbiology (ASM), Australian Society of Cytology (ASC),or the Human Genetics Society of Australasia (HGSA).*"[8] Therefore, in 2007 the NPAAC acknowledged the professional societies as appropriate credentialing bodies with the understanding that the education would allow membership. Thus, by allowing domestic applicants to bypass the only credible assessment of their education, the NPAAC has effectively negated the need for vocational degrees in Australia and any universal oversight of the relevance of Australian degrees.

Internationally, professional societies such as AIMS are used to assess the relevance of higher education degrees for working in pathology laboratories. For example in the UK a Biomedical Scientist must hold a BSc (Hons) degree in biomedical science accredited by the Institute of Biomedical Science (IBMS).[9] In New Zealand a graduate must hold a Bachelor of Medical Laboratory Science or a Graduate diploma in Medical Laboratory Science to be registered and to work in a pathology laboratory.[10] In Canada no one is considered for registration without graduating from a degree program approved by the Canadian Society for Medical Laboratory Science (CSMLS) programs and then passing a certification exam.[11]

The "*Requirements for the Supervision in the Clinical Governance of Medical Pathology Laboratories*" [6] issued by NPAAC defines a "credentialing body" as a; "*formally constituted committee of practitioners and managers who collectively analyze and verify the information submitted by an applicant.*" This definition allows the management of each individual laboratory in Australia to decide whether the applicant's qualifications are adequate for employment. Suggesting that, in the case of medical scientists, anyone who is working in the field is capable of providing primary source verification of every domestic qualification available within Australia and its *"subjects relevant to the field of pathology"*.

One of the main directives of NPAAC that offers an extremely important layer of security for the public, is to ensure a consistent and transparent application of occupational definitions within the pathology environment. This can only be achieved if a single body is responsible for it and as AIMS is already providing the service for international applications. It is the author's view that professional society's involvement is required as a gateway for all graduates.

3) The next recognized level of appointment available to a medical scientist is described as the "Onsite Manager of a Category B or branch laboratory." This role is defined as a scientist with at least two years relevant experience in a larger laboratory. A subset of this role is the Quality Manager which is described *"as a member of staff appointed with delegated authority to ensure that processes needed for the Quality System (QS) are established, implemented and maintained."* Therefore, in a branch laboratory, only the onsite manager may be responsible for this role which adds a large level of complexity to an already demanding role.

In order to effectively manage a profitable and compliant laboratory of any size it would be prudent to have some managerial training, financial education and functional appreciation of human resources concepts. In the UK a Laboratory Manager (Training, Quality or Operational) has a very specific set of well-defined responsibilities to ensure these important, and largely non-clinical obligations support the laboratory. With none of these roles defined in the Australian pathology workforce it would seem beneficial to establish definitions for the future of the service and its workers.

There is an opportunity for the Australian professional societies to demonstrate servant leadership, using the fellowship program as a

vehicle for the role of Laboratory Manager. Fellowship is a well-respected professional qualification around the world and a valuable addition to any resume. It should be used to provide professional recognition of the role of manager in a pathology laboratory.

The requirements for Laboratory Managers should include a Masters' level qualification coupled with a professional fellowship. Currently, fellowship is only available in a clinical discipline and in some instances, it is too specific for many of the regions in Australia. For example, the AIMS Anatomical Pathology Fellowship requires examination in Electron Microscopy. A valuable alternative for many experienced scientists would be the development of a general management fellowship with management, financial and human resources components. This suggested structure is shown in Figure 1.

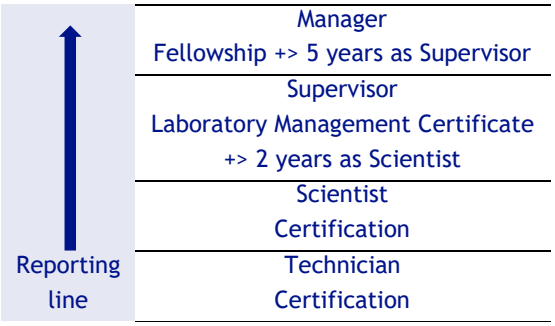

Figure 1: Laboratory Managerial structure

The final level of promotion available to medical scientists is that of a Clinical Scientist which is defined as a scientist who has five years laboratory experience. They must also be in possession of a Doctor of Philosophy or a Fellowship from AIMS, AACB, ASM, HGSA, ASC or Royal College of Pathologists of Australasia (RCPA).

Clinical Scientists hold important positions in a pathology laboratory. Their advanced education is valuable in the clinical setting and provide clinical assistance to Pathologists. Their career pathway is prescribed by the Royal College of Pathologists (UK) and provides a valuable alternative for interested and experienced medical scientists. Medical scientists in Australia can also train under a Pathologist in order to gain a Fellowship of the Faculty of Science of the RCPA.

However, the current definition does not consider PhD graduates of non-clinical subjects such as education or management. It would seem imprudent to label these members as clinical scientists in view of their specialist subject.

Figure 2: Clinical Scientist pathway

Scope of Practice

Any occupation's "Scope of Practice" is a foundational document commonly used to "*describe the procedures, actions and processes that a healthcare practitioner is permitted to undertake in keeping with the terms of their professional license.*"[12] NPAAC has provided a definition of the scope of practice for any pathology worker in the "Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories" which states.

"*The discipline and/or areas of testing in which a person has been trained and successfully examined or assessed as competent by the relevant College, professional society, or credentialing body and in which they have met current Continuing Professional Development and recency of practice requirements.*" [6]

Ironically this definition is more applicable to those countries that require registration of their laboratory workers but seems at odds with the current environment in Australia. The second part of the phrase which mentions competency assessment and CPD requirements, stipulating that this can only be done by "*the relevant College, professional society, or credentialing body*" is difficult for medical

scientists to comply with. Given that there is no relevant college governing medical scientists in Australia, and while a number of professional societies do exist, membership is not mandatory and it has been transferred to NATA to determine competency as part of the laboratory accreditation process in Australia.

However, as NATA does not provide practicing licenses to individuals and is only required to ensure that staff are competent during inspection. The individual laboratories are left to ensure CPD, and that training and competency requirements are met. As the laboratory management can be defines as a credentialing body, can impose any scope of practice that they deem appropriate on their staff. This leads to an inconsistency across the entire pathology service, which can only be addressed through standardization.

The current guidance provided by the Pathology Associations Council in the "*Competency-based Standards for Medical Scientists,*" released in 2009, in consultation with each of the professional societies seems to be the recognized scope of practice.[13] However, the AACB released a *"Scope of Practice of the Scientific Workforce of the Pathology Laboratory"* in 2011.[14] While these documents seem to complement each other there is confusion over which is the official version and who it would apply to within the workforce.

Due to the fact that there is no relevant college or over-arching professional society these documents need to be reviewed with respect to the recently released NPAAC document as the definitions are now out of date. However, as noted, it is of little consequence as the new definition means that it need not be applied unless the laboratory chooses to and this will not be resolved until the NPAAC revises its own definitions.

The role of the certification scheme

AIMS and AACB have proposed a certification scheme for Medical Laboratory Scientists to be implemented in 2020. This project is backed by funding from the Quality Use of Pathology Program (QUPP) which is a national program for promoting initiatives within the pathology services. Some may question why the Ministry of Health recognized that there is enough cause to fund a project of this nature and not use the funds to inject medical scientists into the existing AHPRA framework.

In principle, this project has many redeeming qualities and addresses many of the deficiencies currently facing the profession in Australia. However, it also has identifiable flaws in its own execution; most notably its voluntary nature and inability to sanction practitioners for misadventure. Both of these failings would be addressed by the recognition of medical science as a profession within the AHPRA framework.

Over the course of the last two years there have been a number of stakeholder meetings and the latest update, released in December 2018 contains multiple proposals.[15] Beginning with a lax stance on participation, which highlights important benefits for the public and employees, but fails to press the issue with employers. This approach stands in stark contrast to other health-related professions where participation in a certification scheme is mandated by the Government.

The proposed position for the initial level of certification lowers the required education level for scientists from an AQF Level 8 (Bachelor's degree with Honors) to AQF Level 7 (Bachelors). There is no appreciable reason for this as internationally, an honor's degree is required by the IBMS for employment in the UK, or in New Zealand by the NZIMLS.[9,16] This would mean that domestic applicants would not be required to achieve the same qualifications as their colleagues overseas.

When it comes to entry requirements there is an error in the initial definition of a scientist in Australia. The certification document states, *"The current NPAAC definition of "scientist" has for many years included a requirement of 2 years' professional practice in an accredited laboratory before that role definition can be applied."* [15] In fact, the NPAAC definition of scientist does not prescribe a period of time, this is only

mentioned in the definition of an Onsite Manager of a Category B laboratory. [6] It is beneficial to require a level of professional experience and this should be in recognition of the qualification gained e.g., BSc (Hons) = automatic certification vs BSc + 2 years' post-graduate experience.

On the topic of competency-based certification, much of the discussion seems to be around ownership of the medical scientist's scope of practice. After review of the current document, it is the view of the author that the document is adequate but requires up-dating to reflect modern laboratory practices developed in the last decade. However, it does need to be adopted nationally, because the current NPAAC document allows for too many interpretations of an important function.

The proposal goes on to suggest a framework for CPD and recertification, which is a very important part of the scheme. CPD is critical for providing a quality service, which is a particular failing of the current system as evidenced by the SA Pathology incident of 2016. [17] AIMS provide a robust CPD framework with its Australasian Professional Acknowledgement of Continuing Education (APACE) which would be sufficient if it were to become mandatory for all laboratory workers.

It is the voluntary nature of the proposal that lets it down again with the ability to punish misadventure. This important protection mechanism cannot be applied indiscriminately to different members of the laboratory community based on a non-mandatory requirement. This would be remarkably unfair and the only realistic method by which to achieve this important public security is for mandatory governmental regulation by admission to AHPRA.

In the proposal document, the financial projections are based on 9-year-old survey for the Department of Health and Ageing. [18] From this publication they have estimated a workforce consisting of (senior) scientists and technicians of approx. 14,000. However, the estimated phlebotomy workforce in the survey is 4,083 not the 1,800 that is quoted. The cost of around $300 for certification is reasonable but given the fact that membership is not mandatory nor recognized by employers then certification will pose no value for laboratory workers.

When it comes to ownership and governance, is there any need to create a new body to manage the scheme when the mechanisms already available from the existing professional societies. If we consider that AIMS already has the framework in place to move from a member-benefit professional association to a certifying body if the other societies support its oversight of the program.

A New Fellowship Model

The current fellowship model used by the Australian professional societies for medical scientists is very different for each group.

- The AACB require two written and an oral exam
- The ASM has a 3-part process with an exam, 3 written essays and 5-10 high impact journal publications.
- The ASC require a written, and oral exam, and a 5000-word literature review
- AIMS require 4 written exams, a viva and a doctoral thesis.
- The HGSA send their applicants to the RCPA Faculty of Science program.

The proposed certification scheme is striving to provide a standardized structure for the profession, then a standardized fellowship would also be beneficial. It would seem an unnecessary expense for each society to offer a unique pathway when the entry requirements could be standardized across the profession. The common feature of all of the current models is an oral exam and this should continue to be conducted by experienced members of each distinct society.

The IBMS offer many educational opportunities for scientists, but I would like to highlight the certificates in extended practice that they offer.[9] A recent graduate in any laboratory who has completed an AIMS accredited degree will have enough clinical training to work and will necessarily develop

their skills on the job. If they are considered by NPAAC to be eligible for supervisory positions after two years of employment the professional society should provide easily accessible, basic managerial education specific to their role.

An online offering would be the easiest to develop and maintain and should become a mandatory requirement for prospective Supervisors together with topics in employee relations and financial responsibility. A second offering for Quality managers/officers would be beneficial providing training in health and safety, document management and risk management. With a third for Training managers/officers developed for training and education concepts and competencies. The completion of one of these courses would be the initial step toward a professional fellowship.

A Doctor of Philosophy (PhD) is the highest level of qualification offered by a university for very good reason, it's extremely difficult to achieve. When you consider the time that it takes and the fees that may be imposed it is very hard for anyone working full-time and supporting a mortgage and a family in Australia today. An M-level or Masters' degree is a much more achievable goal and the management structure of a laboratory needs to recognize this, with the PhD being the province of the clinical scientist.

There are many taught Masters' courses, such as a Master of Science (MSc) or Master of Business Administration (MBA), currently available from a number of respected Australian universities, all which would be appropriate for a laboratory manager to have. These could be either science or management based as either would develop skills and education required to be proficient and successful in the role. There is a third avenue, through the Research Training Program available from the Department of Education and Training.[19]

This is a program which essentially removes any fee burden and is provided for research only degrees. This includes the Master of Philosophy (MPhil) program, which requires a shorter dissertation than a PhD, or by publication, which means four journal articles, which could promote the society's journal. This degree can be done remotely and therefore is an accessible route for any regional employee who doesn't live close to a major university and can be on any topic which is relevant to the individual's practice.

Many of the current offerings do not offer the same flexibility, but the main benefit to the societies is that all of the expenses are borne by the universities. The online management programs only need minimal oversight and maintenance which is centralized to ensure relevancy and reduced costs. They only need to conduct the oral exam for prospective fellows who have completed the pre-requisites.

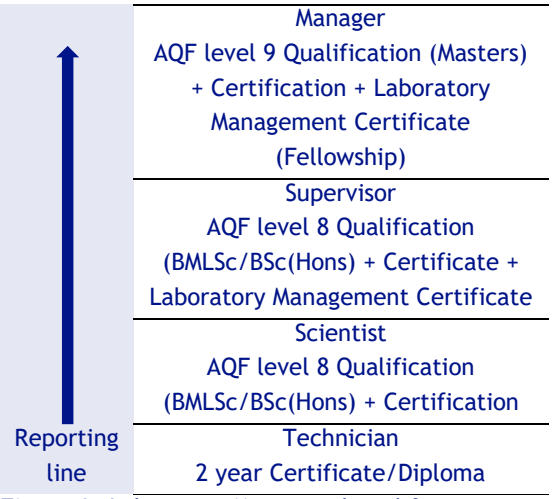

Figure 3: Laboratory Managerial qualifications

Conclusions

In order to appreciate the current career pathway for medical scientists in Australia it is necessary to review the foundational documents governing the occupation. Two documents have been published by the National Pathology Accreditation Advisory Council (NPAAC), whose members are appointed by the Minister of Health to advise on best practice accreditation of the Pathology service in Australia. The two critical documents *"Requirements for Medical Pathology Services"* and *"Requirements for Supervision in the Clinical Governance of Medical*

Pathology Laboratories" and have been reviewed recently to improve clarity regarding the governing principles of the occupation.[5,6]

During this critical evaluation a number of discrepancies were identified that have shown an erosion of the role of the professional society's role in governing the profession. The definitions of the occupational titles have changed between the 3rd and 4th editions, with the professional bodies initially providing credentialing expertise which is now only required for overseas qualifications. The latest edition allows the appropriateness of a domestic qualification and the scope of practice for any Australian medical scientist to be determined by the individual laboratory management.

These fundamental definitions need to be reviewed by NPAAC to allow appropriate control to be returned to the professional societies. This is important for the successful implementation of the proposed certification framework next year. Which is a process that is critical to legitimizing a profession in desperate need of recognition.

In the author's opinion the best way to ensure recognition is by placing authority to govern all aspects of the regulation of medical scientists under the umbrella of the Australian Institute of Medical Scientists (AIMS), not inventing a new entity responsible for administering it. Internationally, a single body is responsible for overall governance of the profession i.e., IBMS in the UK or NZIMLS in New Zealand, in Australia the obvious choice is AIMS. The smaller groups have a place in providing discipline-specific expertise in the awarding of a fellowship.

NPAAC must empower AIMS to provide primary source verification of all degrees domestic and international alike, which allows a standardized application of their scope of practice. The granting of certification following graduation can be applied with respect to degree e.g., BSc (Hons) = automatic certification vs BSc + 2 years' post-graduation.

There is a professional responsibility for experienced scientists to tutor younger members of a society. AIMS should develop online learning tools specifically for prospective laboratory supervisors. These certificates are among a number provided by the IBMS as continuing professional education. The CPD component of professional certification is a critical property that is insufficiently enforced in the Australian medical science profession. AIMS already has a vehicle to provide this with its APACE program.[20]

The profession must also provide transparency for its members regarding promotion requirements, which is currently lacking, as the only provision for supervision of a branch laboratory involves 2 years of working in a general laboratory. The UK model for promotion within the profession provides a useful guide and large number of supportive documents. The most important change from a scientist to a supervisor is the need for some basic managerial education, whether that is operational or as a training or quality officer.

This would ideally be provided online to allow access to medical scientists across Australia. The online format would allow easy maintenance and ensure that the information is relevant to the role. It would only require the development of three distinct certifications i.e., operations, training and quality, to cover any laboratory educational needs.

Currently each of the professional societies in Australia provide different pathways to gain a fellowship which is unnecessarily confusing within the occupation. If the profession is looking to gain respect through professionalism, then this needs to be streamlined. I would suggest that a fellowship for any of the disciplines should consist of a three-part process following initial certification.

First, the scientist must pass the industry manager's certification required for supervisors and, secondly, pursue a Masters' program either MSc, MBA or MPhil as appropriate. Finally, the prospective fellow should undergo an oral examination conducted by experts in their field of medical science. This would substantially simplify the current

process, reduce costs to the societies by pushing the bulk of the work back to universities as education providers and remove a majority of the administration needs from the society's executive.

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