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PATHOLOGY
ACCREDITATION
Advisory Council

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Consultation Phase Response Form for draft NPAAC Documents

Please complete and return this NPAAC Response Form to the Secretariat by the requested date.
It would be appreciated if you could indicate whether the draft document is acceptable in its current form or not.

FROM:

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RESPONSE:

Draft Document Name Requirements for the Supervision of Pathology Laboratories (Fourth Edition 20XX)

I consider the draft document acceptable "as is"	☐
I consider the draft document acceptable "as is" but I have proposed minor suggestions for improvement* **Please refer to my suggestion/responses overleaf*	☐
We do NOT consider the draft NPAAC document acceptable in its present form, and I have proposed various responses for consideration* **Please refer to my suggestion/responses overleaf*	☒

RESPONSE:

General Comments: This response is provided on behalf of the members of the Australasian Association of Clinical Biochemists (AACB) by the Executive following input by members and discussion within the Executive. As the membership of the AACB includes both Pathologists and Medical Scientists we believe we are providing a balanced response to the document. We are impressed with the additional detail in this proposed update compared to the third edition. In particular we commend the following: the updating of laboratory categories to align with current practice; the inclusion of appropriate supervision and quality management aspects for Point of Care Testing; and the increased scope and improved definitions throughout the document. The use of the term Clinical Scientist as distinct from the previous Senior Scientist title is progressive; however the exclusion of this person from the role of Laboratory Director is of concern. This is a significant deviation from previous versions and does not fit current practice in either Australian or Overseas Pathology Laboratories. We acknowledge that Pathologists have greater training opportunities to acquire the necessary competencies required of a Laboratory Director. However, not all Pathologists necessarily automatically become competent to become Laboratory Directors. Similarly, although Clinical Scientists do not have the same range of training opportunities as Pathologists, some do acquire the necessary competencies and experience to become competent Laboratory Directors. We suggest therefore that the key test is whether a prospective Laboratory Director has the knowledge, skills and competence to become a Laboratory Director rather than whether they are a 'Pathologist' or a 'Scientist' and thus favour a process by which to become a Laboratory Director requires the necessary Scope of Practice and managerial experience rather than simply whether the individual is a Pathologist or a Clinical Scientist.

Page no.	S, G or C*	Issue/Item	Response/Suggestion
Page vii	*Definition*	*Clinical Scientist*	*There is some confusion with regard to the addition of a ten year experience in a clinical laboratory requirement for a Doctoral degree. The reasoning for applying a 10 years plus two years experience requirement for doctoral level scientists needs to be more clearly explained. Our understanding is that this relates to the experience requirements for the listed Fellowship qualifications and the training required for Pathologists but this needs to be explained. The removal of PhD as a basis for becoming a Clinical Scientist after 2015 also appears to be counter intuitive as a PhD is something scientists should aspire to. The definition of Clinical Scientist is limited and does not allow flexibility for the future. Business Managers with Laboratory experience should be catered for, new and emerging fields such as proteomics will need engineers to run the HPLC MSMS equipment, PoCT practitioners may not come from traditional science backgrounds (e.g. nursing), and PhDs in science are already emerging in new*

			fields that have not yet impinged on pathology. All of these need to recognize the necessity to import PhD's and/or other qualifications into the pathology field without limiting the career structure by requiring a trade based competency to be enforced. A mechanism for recognizing equivalent (e.g. overseas) qualifications and experience needs to be included. A more appropriate methodology may be along the lines of the UK system and the emerging Pathology Associations Council (PAC) Competency Based Standards (CBS) to define and assess accreditation of Scientists and Clinical Scientists.
Page ix	*Definition*	*Scientist*	*Utilisation of prescriptive qualification sets for the definition of Scientists excludes a number of other possible routes into the Laboratory Medicine field. This is particularly an issue in fields such as Biochemistry, Genetics, Biomedical Engineering and Health Informatics for example where an undergraduate degree is more general than directed Medical Science degrees. A more appropriate methodology would be along the lines of the UK system and the emerging Pathology Associations Council (PAC) Competency Based Standards (CBS) to define and assess competency of Scientists and Clinical Scientists with the Laboratory Medicine specific qualifications as 'bench marks' and other degrees requiring extra training/experience to reach that benchmark.*
Page x	*Definition*	*Scope of Practice*	*Similar to Pathologists, it should be possible for Scientists and Clinical Scientists to extend their Scope of Practice by relevant training, experience and competency assessment. In some professional associations, such as the AACB, both scientists and pathologists sit the same fellowship examinations and similarly in both the UK (with whom we have close parallels in our approach to pathology practice) and in the US, Laboratory Directors may be Pathologists or Clinical Scientists. There is no evidence that the quality of pathology in the UK or US is lower than in Australia. Why is a Clinical Scientist who is able to be a Laboratory Director in the UK or US not able to be a Laboratory*

			Director in Australia?
Page 3	*Categories*	*Category M & P2 Laboratory*	*The distinction between a Category M and a Category P2 laboratory is not clear. They are similar if not identical or at the most a P2 laboratory could be a subset of an M laboratory, and thus there is no need for the separate P2 classification.*
3	*G e)*	*Category P (Point of care Testing) laboratories*	*The definitions of category P (Point of care Testing) laboratories does not include a category that is relevant for the Point of Care Testing "Laboratories" or "Specialised Networks" that are part of the existing well-established networks (iCCnet, QAAMS and Queensland Pathology) These three networks, only one of which is associated with a Category G laboratory, have multiple sites covering a wide geographic area and serve an important function in rural and remote areas of Australia.* *These networks provide a service which is either part of the internal clinical governance structure or are connected voluntarily in the interest of maximizing quality.* *The guidelines for supervision should be expanded to include a category and guidelines for these networks:* *Under e)* ***Category P (Point of Care Testing)****, add:* *(iii) A Category P3 Laboratory which is part of a network providing a Point of Care Testing Service; the network not being part of a Category G laboratory. The network director may be a Pathologist, Clinical Scientist or a Specialist. The laboratories in the network provide a limited range of Point of Care pathology services.* *In* ***Section 6 Supervision and Governance of Category P Laboratories (PoCT),*** *Add the following section:* *c) Category P3 Laboratories* *The standards in this section apply to staffing and supervision of category P3 laboratories only.* *S6.8 The Network facility, its staff and scientific equipment must operate under a single Proprietor at all times.*

			C6.8 The Network must establish, document, implement and maintain an effective Quality Management System. *S6.9 The Network must only provide testing on the limited range of tests for which the network has received accreditation.* *S6.10 The Network Director, under whose direction the Category P3 Network operates must be a Pathologist, Specialist or Clinical Scientist able to demonstrate at the time of accreditation, the following competencies:* *a) Sufficient knowledge, training and experience in the management, operation, monitoring and use of the equipment as set down in manufacturers' manuals, Network manuals and any legislative requirements.* *b) Additional scientific knowledge and experience in the methodology, equipment and analytical (including quality monitoring) procedures in use in the Network, and* *c) knowledge and understanding of all relevant NPAAC documents and other regulatory requirements of a Category P3 Network.* *S6.11 The Network Director, under whose direction the Category P3 Network operates, must:* *a) Ensure that there is a quality management system for the Network which covers and is followed by the Category P3 network site.* *b) Demonstrate control over the monitoring and rendering of services including oversight of supervision.* *c) Review and countersign proficiency testing results or delegate this to a person who is competent in the relevant Class or Classes of pathology testing provided by the Category P3 Network.* *d) Be available for telephone consultation or equivalent when not personally in attendance at the category P3 network site.* *e) Ensure that there is an On- site Supervisor who is an Authorised Operator. In thier absence a suitably*

			qualified operator must be available. *C6.11 a) The Network Director maintains responsibility for, but may delegate the day to day performance of these functions to an appropriately qualified and experienced network coordinator.* *C6.11b) A Network Manager is a Scientist who is qualified in the field of testing in the Category P3 Laboratory and has at least 5 years experience in Point of Care Testing who has management skills and has been appointed to the role.* *In **Section 7 Consultation,** add the following:* *The following applies to Category P3 Laboratories only.* *S7.7 The Network Director and Network Manager (if appointed) must be available for consultation during normal working hours and must have arrangements for at least one of these people to be available and accessible for consultation at all other times.*
Page 4	*S1.2 C1.2*	*The Laboratory Director*	*The revised definitions of G, B, R, and P laboratories specify a Laboratory Director who is a Pathologist. These definitions by default remove the ability of a Clinical Scientist to be a Laboratory Director as is currently possible under the existing standard. The issues with this restriction are many fold:* · *A properly trained, experienced and competent Clinical Scientist should be able to perform this role as is currently the case in a number of Laboratories.* · *The removal of the ability of a Clinical Scientist to become a Laboratory Director in the draft standard introduces a block in the career structure and pathways of scientists within Laboratory Medicine. The potential to lose talented scientists overseas to health systems which do not impose this barrier, such as the UK, is potentially catastrophic. The curtailing of career pathways for laboratory scientists has the potential to impact on recruitment*

			of new scientists into the profession adding further to future workforce pressures. · *The Productivity Commission Research Report of 2005 (Australia's Health Workforce) identified emerging issues and recommended a number of strategies to deal with the impending workforce issues, in particular the development of non-medical practitioner models with allied health scientists being able to practice at a level more historically associated with medical specialists (e.g. Nurse Practitioners, Radiography Practitioners, Clinical Exercise Physiologists etc). The restriction of the ability of Clinical Scientists to act as Laboratory Directors is a contradictory move in the context of the 2005 report and its recommendations.* · *In 2008 the RCPA submission to the Legg Report (The Australian Pathology Workforce Crisis) prepared for the Department of Health and Ageing identified a shortfall of up to 70 pathologists for current positions and over 20% of the current workforce over 60 years of age. The widely acknowledged Pathologist shortage crisis in the coming years makes the new restriction on the qualifications of a Laboratory Director contra-indicative.* · *There is evidence that in rural and regional areas the recruitment of suitable and experienced pathologists in the specialised disciplines is extremely difficult. The Legg Report (2008) recognised the increasing desire of newly trained pathologists to base in larger urban areas with more enhanced facilities and support services to be a major problem. The ability of a Clinical Scientist to undertake direction of pathology laboratories in rural and remote areas would go a long way to providing a complete and safe service in these facilities.*

Page 4	*S1.1 – S1.8*	*Supervision, Governance, Accountability and the Role of the Laboratory Director*	*All aspects within this section are within the capacity and expertise of a properly trained, experienced and competent Clinical Scientist. The arbitrary exclusion of Clinical Scientists without specific evidence of the benefit of the restriction to provision of a safe and cost-effective pathology service is not clear.*
5	*S1.6a*	*The Laboratory Director must be present or readily contactable for consultation during Normal Working Hours of the Laboratory. The period during which the Laboratory Director is absent but contactable must be limited to:* *a) bona fide absences for professional purposes or due to illness or personal necessity for up to seven consecutive work days, but for no more than 28 work days in a calendar year, after which a replacement must be nominated for and who must take up this position without any break of continuity of supervision*	*It is unclear whether this includes, or is independent of, annual leave.*
Page 6	*S2.3 and S2.4*	*Laboratory Director*	*As discussed above there is no clear reason given why a properly trained, experienced and competent Clinical Scientist could not fulfil the role of Laboratory Director within a Category G laboratory, whether single class or multi class, under the same conditions of training, experience and competency assessment as a Pathologist.*
Page 6	*S2.5*	*Supervision of Class of Pathology Testing*	*We support this clause but feel the intent of the clause (i.e. role substitution) should be applied across the document and up to the level of Laboratory Director.*
Page 7	*S3.3*	*Laboratory Director*	*As discussed above there is no clear reason given why a properly trained, experienced and competent Clinical Scientist could not fulfil the role of Laboratory Director within a Category B laboratory.*
Page 7	*S3.5*	*On-site supervision of Category B Laboratories*	*Laboratories that fit the definition of Category B laboratories can be quite large and complex facilities, particularly in rural and regional areas. The supervision requirement of Scientists with 2 years' experience or a Technical officer with 5 years' experience is manifestly insufficient for these laboratories. Understanding the intent of this clause in regards to the problems with recruitment into Category B laboratories we favour the retention of the*

			current clause which allows for lesser qualified individuals but with ongoing attempts at recruitment of appropriately qualified scientists (not Technicians). A move to formalize the employment of Technicians into such positions carries the risk of 'lowering the bar' and thus quality of Category B laboratories.
Page 11	*S4.3*	*Laboratory Director*	*As discussed above there is no clear reason given why a properly trained, experienced and competent Clinical Scientist could not fulfil the role of Laboratory Director within a Category R laboratory and in fact Category R laboratories, as outlined in S4.4, are examples of laboratories where a highly trained, experienced and competent Clinical Scientist would be a more logical Laboratory Director where Pathologists and/or Specialists are rare or unavailable to direct the laboratory due to ongoing clinical requirements (e.g. genetics).*
Page 15	*Category*	*Category P2 Laboratories*	*The distinction between a Category M and a Category P2 laboratory is not clear. They are similar if not identical or at the most a P2 laboratory could be a subset of an M laboratory, and thus there is no need for the separate P2 classification.*
Page 18	*Appendix A*	*Laboratory Director must be a Pathologist with management experience*	*This is very vague (i.e. what management experience is required) and as discussed above there is no clear reason given why a properly trained, experienced and competent Clinical Scientist could not fulfil the role of Laboratory Director.*
Pages 19 to 29	*Classification of Tests*	*Classes of Tests*	*It is not clear from the classification what defines a G Class Single Test Group or multi test group laboratory where it is proposed Clinical Scientists will still be able to occupy a senior management role. Does this include major classes of tests (biochemistry, haematology, microbiology etc) or sub-sections (immunoassay, chromatography, blood-bank etc)? This needs to be more clearly spelt out as it has implications for both the definition of Laboratory Director and Supervision of these laboratories.*

Please note:

- ***The NPAAC Consultation Phase Response Form is in Word format to assist you in providing comments on the draft NPAAC document. To assist the Secretariat in collating responses, it would be appreciated if the template was not structurally modified.***
- ***Adding extra table rows or pages is acceptable as required***
- ***Responses can be forwarded to the NPAAC Secretariat in the mail MDP 852, GPO Box 9848, CANBERRA ACT 2601 or via Email – npaac@health.gov.au***