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National PATHOLOGY ACCREDITATION Advisory Council

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Consultation Phase Response Form for draft NPAAC Documents

Please complete and return this NPAAC Consultation Phase 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, and any potential regulatory costs associated with compliance to the proposed requirements.

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 via Email – npaac@health.gov.au and by post to NPAAC Secretariat, GPO Box 9848 (MDP 951), CANBERRA ACT 2601

FROM:

	Ms	**Date**	November 2016
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RESPONSE:

Draft Document Name: Requirements For The Clinical Governance And Supervision Of Medical Pathology Laboratories

I consider the draft document acceptable in its present form	☐
I consider the draft document acceptable "as is" but I have proposed minor suggestions for improvement* **Please refer to my suggestion/responses overleaf*	☐
I 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*	X

SUGGESTION/RESPONSE OVERLEAF:

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
13, 15	Introduction	Public pathology organisations have quality systems, accreditation and governance processes in place which take into account the geography/demographics, services and scope of the laboratories within each organisation. Introduction of stringent guidelines may take away the ability to structure services appropriately with regard to the volume and type of tests provided by different laboratories. The requirements do not identify what suboptimal or inappropriate supervision practices are, or how they are to be addressed. The draft Requirements are inconsistent with the current legislative framework which does not mandate a Pathologist with a 'scope of practice'. A practical implication of the draft Requirements will be for laboratories to change from a Category G to Category B without changing the services provided and overall supervision will decline as a result. This is against the intention of the Requirements.	The guideline should be consistent with current legislation and AS/ISO 15189 standards. Suboptimal or inappropriate supervision practices could be defined, including processes for how they are to be addressed. The Implementation Guide should be provided for review and comment prior to the guideline being implemented. NATA must be fully briefed by NPAAC in relation to the Requirements and any points of ambiguity clarified. The impact of changing from a Category G laboratory to a Category B laboratory should be considered.
15, 20 etc	S1.1, S1.2 3B. S3.5, C3.5(i) etc	Whilst adherence to NPAAC standards is required under the Health Insurance Act to bill Medicare, NPAAC standards are used more broadly to ensure quality laboratory practice. Under the requirements, there would need to be multiple APPs for each Category G laboratory. However, it is more appropriate that supervision is	Remove reference to an APP.

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		delegated to those who are competent to provide it, rather than an APP. The quality of supervision is not improved purely by virtue of the supervising pathologist being an APP. All supervisors have a duty of care regardless of whether or not they are also an APP. Billing requirements should remain separate to supervision requirements. If this is not changed, there is a risk that some laboratories who do not bill Medicare will reduce their level of laboratory classification.	
v, 15, 17, 19 etc	Scope, 1. 1) Category G S1.2, 3A, S3.2(ii) etc	To meet the 'scope of practice only' requirement, a consultant for each discipline would have to be present within each G laboratory, regardless of the complexity and the number of tests performed. This impacts services where pathologists are either not always on site, or are part time or jointly appointed, but are still contactable. There are HR implications for these staff if the change is instituted. There is a need to question the cost of this versus the value add given the scope of testing and availability of supervision remotely through videoconferencing, hotlines, etc. This approach is contrary to the current strategy of using a telehealth approach to provide services to reduce costs and ensure equity of service provision which is particularly relevant to geographically dispersed services. It is not clear that the required number of specialist pathologists could be sourced. Even if they could be, the financial implications are considerable and backfill is also likely to be an issue. Allowance should be given in cases where recruitment of specialist	Consistency with the related Tier 2 document is required. There must be consideration of the complexity and number of tests provided. This would make the Requirements consistent with the accompanying NPAAC Tier 2 document. The Requirements for Medical Pathology Services states that the specific requirements for governance and supervision will differ according to the complexity of testing and category of the laboratory. There should be an exemption from having to have full time on site specialist pathologist supervision based on an ability to demonstrate appropriate supervision considering the volume and complexity of testing and category of laboratory. Fractional appointments of supervisors should be permissible depending on the needs of the laboratory and presence of clear governance/quality frameworks.

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		pathologists has been pursued but not successful and appropriate delegation given to Clinical Scientists. Risk management and assessment is included within the definitions, however there is no consideration given for the pathology entity to make risk-based decisions based on the complexity of the tests performed, the number of tests performed, the qualifications and experience of the scientific staff, and the level of pathologist supervision required, e.g., a Group Laboratory with associated B laboratories may do limited microbiology, under the supervision of a 0.2 Microbiologist. B laboratories may do limited Microbiology and send to a Group Laboratory under the Supervision of a fulltime Pathologist. There are jointly trained Pathologists supervising G/B laboratories with limited tests under the scope.	Clarification of 'full time' supervision is required in the context of the normal working hours of operation of the laboratory.
		The Requirements may prompt Category G laboratories to reclassify as Category B laboratories. However, there may be implications where public hospitals have stipulated specific categories of laboratories in service level agreements with pathology providers. Similarly, some state governments have instituted Clinical Services Capability Frameworks which outline service descriptions and service requirements pertaining to the level of pathology services required for the level of public and private hospitals serviced based on the current NPAAC Requirements. Given the number of public hospital networks serviced and mechanisms of state government, considerable time would be required to negotiate changes to the	Transition timeframes may be required. Exemptions based on demonstration of appropriate supervision must be considered.

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		agreements. It may not be possible to negotiate changes to the broader Clinical Services Capability Frameworks. There are also cases where a Category G laboratory is unable to change to a Category B laboratory as there are no other laboratories servicing the Public Hospital Network. Effective supervision is still possible even though there are no full time specialist pathologists for each group of tests, given the volume and complexity of testing and employment of appropriately skilled scientists.	
19	S3.2(iii)	Limiting delegation to a full time pathologist within scope has practical implications where the volume of work cannot justify a full time pathologist or a particular type of pathologist cannot be recruited. General Pathologists are recognized by the RCPA and NATA. However, the Requirements do not clarify the role of a general pathologist in terms of supervision and delegation.	The designated person should be able to delegate to another Pathologist or Clinical Scientist with the relevant scope of practice. The role of a general pathologist and their ability to delegate supervision must be clarified.
7 17	Definitions 2. Category G 1) b)	There is an issue with the definition of Clinical Scientists. The reduction from 10 years in the previous Requirements to 5 years' experience is appropriate (assuming the experience is relevant in the context of supervision). However, there are a limited number of scientists holding Fellowships in the industry and the lead in time for the number of required staff to obtain Fellowships to meet the requirements is significant.	Remove the requirement for a Fellowship or PhD and replace with the words 'appropriate postgraduate academic qualifications'.

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		The requirement to hold a Fellowship is provided more weight than a scientist with proven capabilities and laboratory experience. This model would preclude experienced scientific staff from performing supervision. A PhD may not be relevant to the ability to provide effective supervision. Many competent scientists hold Masters degrees rather than PhDs.	
17, 19	2. 2) Category B. c) 3. 3A. S3.2 (i), (iii), S3.4	The governance model appears to be based on one Category G laboratory overseeing several Category B laboratories under the one entity. However, in a large Pathology Network there may be multiple Category G laboratories under the one quality system. Supervision restricted to *one* Category G laboratory within a Pathology Network reduces access to available resources and expertise whilst increasing financial and resourcing requirements. It limits the ability of organisations with multiple laboratories to efficiently supervise laboratories. For example: • Ability to supervise from other G laboratories with pathologists conducting supervisory visits across the Pathology Network. • Does not take account of models such as Discipline Working Parties which develop policy and provide guidance/oversight across all laboratories in the Pathology Network. • Does not consider Pathology Network-wide clinical support hotlines, LIS and other quality and corporate governance systems that have capacity for remote oversight (e.g. review lists,	Restriction to one category G laboratory should be removed.

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		LIS flags where further test/oversight is required).	
20	3B. S3.5(ii)	Requiring the "Quality Manager" to visit each laboratory at least once a year would require additional resources that wouldn't necessarily add value, particularly considering the existence of alternative corporate governance structures (e.g. monthly quality meetings, annual compliance audits).The Quality Manager should be able to delegate to an appropriate officer.	The Quality Manager should be able to delegate to an appropriately qualified officer.
20	3B. S3.6	The requirement for two FTE days per year is significant for those laboratories that perform limited tests. This has financial and resourcing implications, particularly for rural laboratories. There may already be in place regular quality meetings, discipline working parties, teleconferences, and Pathologists on duty and on call at all times. A Scientist should be acceptable.	Include Scientists in all points including B laboratories providing POCT only.
21	3C. S3.10 a)	Omits Scientist while S 3.10 (e) includes Scientist.	Include Scientist.
21-23	3C. S3.10 C3.10	Pathology laboratories cannot dictate to hospitals the type of services the hospitals use outside the pathology department. The laboratory may not own, control, be responsible for, or bill for tests performed on the POCT device, however this implies that the device is to be included within the laboratory's scope of accreditation.	The wording needs to be flexible such that a laboratory can nominate which devices in hospitals will be accredited by the laboratory.

POTENTIAL REGULATORY IMPACT INCLUDING COSTS, ASSOCIATED WITH COMPLYING WITH PROPOSED REQUIREMENTS

1. Do you expect that additional activities will be required in order for your laboratory to comply with the revised Requirements?

X Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required to carry out the additional activities?

TBA

(b) What additional staff to you estimate will be required to carry out the additional activities?

TBA. Considerable number of additional staff if full time onsite pathologist supervision for each group of tests was required.

(c) What costs to you estimate will be incurred as a result of the additional activities?

TBA. Costs would be significant.

(d) Will these costs be one-off or ongoing?

If laboratories recruit additional staff to ensure compliance then costs would be ongoing. Costs would be one-off if laboratories change their classification.

2. Do you expect that changes to existing processes/procedures or infrastructure will be required in order to comply with the revised Requirements?

X Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required as a result of these changes?

TBA

(b) What additional staff to you estimate will be required as a result of these changes?

TBA

(c) What costs to you estimate will be incurred as a result of these changes?

TBA

(d) Will these costs be one-off or ongoing?

TBA

Any additional general comments including any potential costs associated with compliance to the proposed requirements (please provide specific examples):

A financial and feasibility impact study should be performed prior to the implementation of these guidelines to evaluate the impact of these new regulations to the industry and whether it would actually improve governance and quality of supervision provided.