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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** | 27 January 2020 |
| **First Name** | Jenny | **Last Name** | Sikorski |
| **Position Title** | CEO | **Organisation** | Public Pathology Australia |
| **Address** | *Suite 154, 4/16 Beenleigh Redland Bay Rd, Loganholme* | **State** | Qld |
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**RESPONSE:**

**Draft Document Name: REQUIREMENTS FOR THE COMMUNICATION OF HIGH RISK PATHOLOGY RESULTS (First Edition 20XX)**

| | |
|---|---|
| **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* | ☐ |

**SUGGESTION/RESPONSE OVERLEAF:**

| Page no. | S, G or C* | Issue/Item | Suggestion/Response: |
|---|---|---|---|
| vii | Definitions | 'High risk result' definition should be improved. A 'result' per se does not 'pose a risk to the patient' the condition that induced the aberrant result poses the risk and the result is indicative of the degree of 'risk'. This definition does not give any indication of the consequences of this risk that would dictate the categorization of 'high risk', ie. Immediate or imminent risk to life? | Amend accordingly. |
| 1 | Introduction | Missing full stop after first sentence, first paragraph. | Insert full stop after first sentence, first paragraph. |
| 1 | Introduction | Use of PoC abbreviation is confusing. | Replace "POC services" with "Point of Care Testing (PoCT)". Also define PoCT consistently with the NPAAC PoCT Requirements and include in definitions in page (vii). |
| 1 | Introduction | Missing full stop after citing ISO 15189. | Insert full stop after citing ISO 15189. |
| 3 | 1 | Full stop in wrong place at start of 3rd paragraph. | Remove full stop from start of 3rd paragraph. |
| 3 | 1 | 'ACQCHC' is the incorrect abbreviation for the Australian Commission on Safety and Quality. | Amend and include in Abbreviations on vi. |
| 3 | C1.2 | Missing comma between NPAAC and Medical Board references. | Insert comma between NPAAC and Medical Board references. |
| 3 | S1.3 | Relevance of Appendix A could be stated. | Amend to "Refer to Appendix A for examples." |
| 4 | C2.1(i) | Commentary could be improved by detailing more about competency. | Consider by whom, and how is the individual to be judged as competent and how is this adjudicated and recorded. What is the competency that should be recorded? |
| 5 | C2.45(ii) | Incorrect numbering. | Replace C2.45(ii) with C2.4(ii). |
| 5 | CC2.5 (ii) – iv) | The commentary which uses the word "should" appears inconsistent with the standard which uses the word "must". | Replace "should" with "must". |

| Page no. | S, G or C* | Issue/Item | Suggestion/Response: |
|---|---|---|---|
| 6 | S2.6 | PoCT Operators outside Laboratory-managed PoCT Networks generally do not report to Laboratory staff. | Replace with "When PoCT is governed by a Laboratory and used in acute care settings (e.g. Emergency Departments), the Laboratory must have procedures for the PoCT Operator to notify a relevant clinician of high risk results." |
| 7-11 | 3-6 | Missing specific standards from Requirements for Medical Pathology Services. | Insert specific standards from Requirements for Medical Pathology Services. |
| 3 | C3.21(i) | Missing full stop after "Inadequate sample." | Insert full stop after "Inadequate sample." |
| 10 | C5.3 | Bullet point in wrong location. | Amend bullet points. |
| 12 | 7 | This is a statement of consumer rights that provides context for the document and should be included in the Introduction rather than as a Standard. | State consumer rights in the Introduction and remove Standard 7. |
| 18 | Appendix B | Confirm whether it is the positive blood culture alone that initiates the notification protocol or when the organism is identified. | Amend accordingly. |
| ** Standard or Commentary* | | *** Example of how to complete the form* | |

## 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?**

☐ Yes ☐ No

**If Yes:**

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

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

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

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

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

☐ Yes ☐ No

**If Yes:**

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

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

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

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

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