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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**	21 December 2018
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RESPONSE:

Draft Document Name: Requirements for Laboratories reporting tests for the National Cervical Screening Program (2nd edition)	
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:
		Please note that the following represents the views of the majority of PPA member respondents.	
2	*Introduction*	Consideration of data available from the first 6 months of the NCSP has indicated that the rate per 2000 is not currently functioning as a useful quality indicator, the rates in individual laboratories being affected by factors including demographic differences in tested populations and differences in classification of screening episodes. While comparison between a laboratory's positivity rate and the national rate is still considered a necessary benchmarking exercise, reporting of rates outside the confidence limits to the NCSR is no longer mandated as a standard. Over the last 12 months, performance measures in effect measured a combination of test performance AND population characteristics. It is not possible to determine the relative contributions of these two factors to the overall local or national data. Confounding factors have been shown to severely limit or invalidate the results, especially variations in HPV prevalence. Laboratories cannot compare their performance against other laboratories, not least because NPAAC has not published any de-identified data for the entire 12 months that these performance measures have been operation.	The fact that individual laboratories are affected by demographic differences in tested populations and differences in classifications of screening episodes demonstrates that comparison to a national rate may not appropriate for benchmarking. The approach violates the statistical principle that a sub-population should be representative of the comparator population and vice versa. Therefore, PPA agrees that the 2000 specimen minimum limit be removed. The change which requires reporting benchmarking results that fall outside the confidence limits to monitoring only makes this measure less onerous for laboratories and takes into account the variation in patient populations in different catchments that laboratories service.
7	*S3.5*	The HPV NAT material must be retained in accordance with S5.5[1] of the Requirements for the Retention of Laboratory Records and Diagnostic Materials.	There is no 5.5 in the linked document.

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
			Recommend removal of s5.5 reference in the linked document.
7	*S3.6*	The residual sample, where LBC has been performed, must be retained in accordance with the manufacturer's instructions, for a period of at least one month after the report is validated in accordance with S5.5 and with the Requirements for the Retention of Laboratory Records and Diagnostic Materials. Retention (Non-screening (diagnostic) tests).	There is no 5.5 in the linked document and S5.5 in the current document is not related to sample retention. **Recommend removal of s5.5 reference in the linked document.**
11	*S5.5*	If a reagent batch failure is detected by a laboratory, the NCSP must be informed immediately so that other users can be notified.	Normally a failure would be investigated, rectified and re-run. It would only be appropriate to report externally if a systematic issue was detected, or if an issue cannot be rectified; e.g. if a reagent batch was faulty, and there is possibility of impact to other providers. **Recommend that this be clarified.**
12	*S5.6 (i)-(iii)*	Laboratories must compare their rates of HPV detection in screening tests with the rates most recently reported by the NCSR. C5.6(i) The NCSR will use the routinely submitted data to produce a periodic age stratified data set (including mean and 95% confidence interval) compiled from data from all HPV testing throughout Australia. C5.6(ii) If the laboratory's HPV positivity rate in screening tests is not within the 95% confidence interval, the laboratory must investigate the cause (refer to Appendix A). C5.6(iii) Each of these activities must be monitored at least quarterly and the results or outcomes recorded.	Some members have questioned the need for a comparison between a laboratory's positivity rate and the national rate. The statistically-derived confidence limits are only valid if the body of data used to determine it are multiple samplings of the same homogenous population. Such confidence limits therefore specify acceptable ranges of positivity due to 'random' variation. The aim of benchmarking is to detect 'systematic' (i.e. 'non-random') variation due to a diagnostic system failure. However, since each laboratory does not actually sample the same population, the confidence limits are not valid. In fact,

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			differences in population demographics (e.g. age, numbers of sexual partners, vaccination status) would be a key reason for values obtained outside the confidence limits. This is a key source of 'systematic' (i.e. 'non-random') variation that has nothing to do with a diagnostic systems failure. The testing population for some public pathology providers is not comparable to the national rate, and a variance is expected. To require the laboratory to undertake further investigation is a large cost exercise that not only has no value, and if the laboratory were to meet the benchmarking, this would in fact indicate that the assay was under-detecting HPV. The introduction to this document clearly identifies that this difference in population positivity has been confirmed in NCSR data. NCSR could continue to provide positivity data for longitudinal public health purposes. **Recommend removal of comparison between a laboratory's positively rate and the national rate or further clarification in light of comments immediately above.** One PPA member noted that a better way to ensure integrity of HPV DNA screening in the laboratory would be to issue and monitor (nationally) the various laboratories' platform-specific assay results based on testing of standardised QC materials and standardised EQA samples on a more regular basis. For example, the

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			National Serology Reference Laboratory's EDCNet where participating laboratories across Australia and other countries can enter their individual data from known QC materials for testing for organisms of public health importance (e.g. HIV). Each contributing laboratory can compare their own QC data to the aggregate data of other participating laboratories in a platform-specific, QC material-specific manner to detect if their assay is performing correctly. Laboratories can also monitor the performance of their QC materials internally to detect run failures. NRL and RCPA QAP also issue EQA samples which enables peer group comparisons. For laboratories testing samples as part of the NCSP, enhanced monitoring of QC and more frequent standardized EQA samples would be a good way to ensure quality results. The use of internal laboratory control charts, such as P-charts, for ongoing monitoring of laboratory-specific positivity rate (as stated in Appendix A) may also be helpful, provided that the test population has relatively stable demographic differences. Benchmarking of positivity rates in comparison to national data is a flawed process based on incorrect assumptions about populations tested.
12	*C5.7*	Each of these activities **must** be monitored continuously and the results or outcomes recorded.	It is not feasible for laboratories to develop real-time monitoring of these quality measures to meet the "continuous" requirement. Data collection and analysis is complex, some data can only be collected months after the LBC, and some data is only provided by the NCSR at quarterly intervals or less. Currently, raw

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			data is not being provided by NCSR which makes this even more difficult. **Recommend the appropriate frequency be quarterly** (as per C5.6(iii)). **NPAAC should also require the NCSR to provide raw data to pathology laboratories**, as patient matching to NCSR ID is within the NCSR responsibilities.
13	*S6.2*	The content of the report must include an overall cervical screening risk classification, specimen type, test results and management recommendation.	The Guidelines do not provide an overall cervical screening risk rating for diagnostic specimens, so this should not be a requirement. A risk rating is not appropriate in certain situations, such as a patient at higher clinical risk, current malignancy. **Recommend a change so that "overall cervical screening risk classification" is only a requirement for screening cases.**
13	*S6.3*	The report format and management recommendation must be in accordance with the NCSP 2016 Guidelines2 and must take into account the previous screening history from the NCSR.	Reference is made to "NCSP 2016 Guidelines2" when there has only been a single published set of Guidelines. **Recommend removing "2".**
13	*S6.5*	Laboratories must report 90% of all cervical screening specimens within 10 working days of receipt.	The 10 working day limit is severely impacted by the delays in patient histories from the NCSR. A slightly longer timeframe is clinically acceptable and previous programs have allowed 20 working days. As this requirement is only for screening, delays to the receipt of NCSR histories to the laboratory, or other issues, mean that screening specimens may need to be

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			prioritized over diagnostic specimens; this does not reflect clinical risk and need, and may, therefore, be inappropriate. **Recommend change of S6.5 to 20 days for 90% of screening and diagnostic cases and include a requirement for NCSR to return history within 24 hours**.
15	*S7.1*	Performance Measure 1 is an inadequately described screening test rate.	Performance measure 1 is heterogeneous in that it contains inadequate hrHPV tests and inadequate triage LBC tests. NPAAC and RCPAQAP should be aware that the proportion of 'unsatisfactory' episodes may be dependent on many factors outside of the control of the testing laboratory (e.g. poorly taken samples with inadequate numbers of cells, presence of inflammation, blood staining of sample, patient use of lubricants or interfering/inhibitory substances). These pre-analytical factors can have an impact on both HPV DNA and LBC testing. The laboratory cannot be made responsible for factors related to obtaining the sample from the woman. **Recommend changing Performance Measure 1 accordingly.**
15	*S7.4, S7.5*	S7.4 The proportion of LBC specimens reported as HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP. C7.4(i) This must be reported to the RCPAQAP by October in the following year.	This requires data from the NCSR. **Recommend include a requirement for the NCSR to provide this data at least two (2) months prior to the reporting date.**

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
		C7.4(ii) Where multiple histopathology reports fall within the six month period after the cytology report, the case must be compared with the highest grade of abnormality in the histopathology reports. C7.4(iii) No numerical standards have been set yet. Performance measure 3b S7.5 The proportion of LBC specimens reported as possible HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP. C7.5(i) This must be reported to the RCPAQAP by October in the following year. C7.5(ii) Where multiple histopathology reports fall within the six month period after the cytology report, the case must be compared with the highest grade of abnormality in the histopathology reports. C7.5(iii) No numerical standards have been set yet.	
16	*S7.6*	The proportion of women with histological diagnosis of HSIL or malignancy which were originally reported as low risk with a primary screening HPV NAT within the last 63 months must be reported.	This requires data from the NCSR. **Recommend requirement for the NCSR to provide this data in a timely manner.**
15-16	*S7*	If performance measures for triage cytology is required, then meaningful subsets of results should be examined.	Analysis of triage cytology results can be optimised by looking at meaningful subsets. These measures could be split into two groups, namely triage cytology in HPV 16/18 negative women and triage cytology in HPV16/18 positive women. PPVs for each triage cytologic prediction could also be calculated. This would minimise the effects of population characteristics more reliably than using vaccinated and non-vaccinated cohorts.

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			NPAAC should request a data extraction from the National Cervical Screening Registry for triage cytology in the HPV16/18 positive and HPV16/18 negative groups, for the first 12 months of operation of the new screening program. This data should be made available to all laboratories, since this national data will prove invaluable to laboratories in assessing their own performance.
15-16	*S7*	There needs to be clarification regarding classification of a specific subset of women returning for HPV DNA screening. Commencing in December of this year, women who have had a previous positive HPV test but who are ineligible for immediate colposcopy will return for repeat hrHPV testing. These hrHPV are screening tests, yet the NPAAC document does not give details of how they should be handled.	**Recommend hrHPV tests be treated separately for statistical purposes.**
17	*Appendix A*	*All*	The detection rate of some public pathology providers is expected to be outside the national reference range, due to patient demographics, and therefore these actions may not be clinically appropriate and may be a wasteful use of public moneys. The Requirements for Medical Testing of Microbial Nucleic Acids, as referenced elsewhere, describes a more appropriate approach. **Recommend removing this appendix.**
19	*Appendix C*	*Contact data items: Residential address, residential suburb/town/locality name, residential state/territory name, residential Australian postcode*	These are stated as mandatory items, which is inappropriate. We do not receive an address for vulnerable populations which may include itinerant persons, sexual health workers, incarcerated persons, or persons located in areas that do not have the

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			accepted address criterion (such as remote communities). A mandatory approach means that the program is excluding these vulnerable populations from the benefits of screening. The Australian Department of Health has agreed that these patients should be accepted by the NCSR. **Recommend change to "Report if available."**
		Provider data items: Medicare provider number	This should not be a mandatory item, as public practitioners (with a valid AHPRA number) who do not engage in private practice will not have a Medicare provider number. The Australian Department of Health has agreed that these patients should be accepted by the NCSR. **Recommend change to "Report if available."**
		HPV Test Group, Cytology Test Group	Coding in these tables doesn't match the LOINC provided by Telstra Health, and which has been implemented in the NCSR as well as individual Laboratory Information Systems. **Recommend updating, and for this table to be a guide only, with reference to the RCPA SPIA (Standard for Pathology Informatics Australia).**
		Please note that only one member responded that they were happy with the document in its current draft state.	

** 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?

Significant extra time – estimated 40 hours per week for a single pathology provider as stated by Pathology Queensland (PQ). Similar impacts may be experienced by other public pathology providers and this would require further analysis.

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

At least 1 x FTE above current staffing levels for 1 provider (PQ).

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

Costs of extra staff as well as maintenance of software to support statistics and monitoring.

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

Both.

Statistics: One-off costs to set up the statistics software and templates; on-going costs to collate, clean and analyse data.

Data fields: one-off costs to introduce changes in the LIS to provide "default" values, or to stop patients with missing data going to the NCSR, then on-going costs managing missing data.

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?

1 day per month ICT support time, + processes described above for laboratory staff for 1 provider (PQ).

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

0.2 FTE for 1 provider (PQ).

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

ICT support and software maintenance costs as well as any software enhancement costs – unable to estimate but likely to be significant (>$50,000) for 1 provider (PQ).

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

Both

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