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SUBMISSION #:

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
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RESPONSE:

Draft Document Name: REQUIREMENTS FOR INFORMATION COMMUNICATION AND REPORTING (Fourth 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*	X

SUGGESTION/RESPONSE OVERLEAF:

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
		General Comment	This document could benefit significantly from a rewrite and clarification. As these Requirements will probably outlive SPIA or other standards/products and the reference sets are under development, it is better to state the overarching requirements and reference the standards/products rather than including detailed aspects of the standards/products in the Requirements. It is important to emphasize that Laboratories must have a sound information governance framework in place, especially with respect to interoperability, which includes a roadmap for SPIA compliance. There should be reference to the following standards/products and a notation that these products may change over time: • SPIA • the RCPA reference sets published on NCTS • the current HL7 Australia standard for diagnostics messaging, • FHIR data standards. Consideration could also be given to including SSL, VPN, Ack, SMART and API.
v	Scope	Consideration should be given to increasing the scope to include data quality and the presentation of digital information for interoperability, as it is not possible to	Amendment to the scope could read: "The information that the Laboratory presents to interoperable systems and

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
		ensure the quality of information communicated if the source is poor.	consumers must be secure (available, confidential, authentic, accurate, complete) and of a high-quality (both content and structure)." Standards in relation to data quality could be referred to in the body of the text.
viii	Definitions	Proper citation of Healthcare Provider Identifiers for Individuals, Organisations and Individual Healthcare Identifiers plus their abbreviations (HPI-I, HPI-O, IHI) should be included as these are used on p18.	Amend accordingly.
x	Definitions	Structured reporting definition could be improved.	Definition could adopt the SPIA definition.
12	Introduction	This section could benefit from more broadly stating the intention/overarching objective.	The following wording could be included before the 2nd paragraph: Laboratories must recognise the importance, and conduct due diligence, for the management of their pathology information asset as an interoperable component of the national digital health landscape. Should data quality be included in the scope, the following wording could be adopted at the conclusion of the current 2nd paragraph: "It also means that Laboratories should invest in continuous improvement, emerging standards and technologies, as well as an appropriately skilled workforce and business processes, to enable pathology data quality across the healthcare continuum."
12	Introduction	Ensure correct reference to HL7 is used.	Refer to the current version of HL7 Australia *Australian Diagnostics and Referral Messaging - Localisation of HL7*. At the date of publication, this is Version 2.4.

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12	Introduction	It is useful to include the graphic outlining laboratory messaging in context as an overview of all the messaging that falls under these Requirements.	Include suitably updated Figure 1 from the Third Edition of these Requirements.
12, 14	Introduction and governance	There is a need to clarify whether the Requirements pertain to Information Governance (managing the information asset) and / or ICT Governance (managing the technology asset). Public pathology providers typically have responsibility over Information Governance but not ICT Governance which is usually under an IT Services Department. Consider whether there needs to be further attributes assigned to the designated person relevant to information communications as occurs with other NPAAC documents.	Clarify accordingly.
14	Governance	Reference to Appendix B is omitted.	Include reference to Appendix B after the first sentence.
14	C1.2	Sentence would benefit from clarification.	Replace with "Investigations of potential data security and privacy breaches and failures to transmit…"
15	S1.4	Full stop omitted.	Insert full stop.
16	S2.1(a)	Commentary could be provided to describe the point up to which the Laboratory is responsible.	For example, Laboratories are responsible for he completeness, accuracy and integrity of electronic messages until the message is: • decrypted at destination system if using end-to-end PKI; • received by middlewear; • consumed by integration platform if sent via an enterprise integration engine.

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
18	S3.2	As this relates to patients, practitioners and organisations identifiers rather than individual IHIs should be referred to.	Replace "IHI" with "identifier".
18	C3.4	Inconsistent use of upper and lower case "L" for Laboratory.	Amend consistently throughout.
18	S3.4	Should this be in the terminology and codes section?	Check location.
19	4	The first paragraph is confusing. Mandating compliance with the current HL7 version could prove challenging as it may not have been implemented yet. It could also be costly for Laboratories to implement. It is therefore important to include a roadmap towards compliance.	Amend the paragraph so that it reads correctly. Laboratories should comply (or have a roadmap outlining how they are working towards compliance) with the current Australian Diagnostics and Referral Messaging – Localisation of HL7 published by HL7 Australia.
22-23	6 A-C	Confusing use of subheadings for Requesting Terminology and Codes	Delete subheadings A, B, C and replace with Requesting Terminology and Codes.
23	S6.3	This reads as if there is a degree of choice.	This could be replaced with: "Laboratories must adopt (or demonstrate a roadmap to compliance) the RCPA terminology reference sets published on the National Clinical Terminology Service."
23	C6.3(ii)	Full stop omitted.	Insert full stop.
24	C6.65(viii)	Should be C6.5(viii). Additional space between off – screen.	Amend to C6.5(viii). Remove space within the word off-screen.
25	C6.5(xx)-(xxiiii)	Incorrect numbering.	Amend from C6.5 (xix) concluding C6.5(xxii).
25	C6.5	Extra space between C6.5(xxi) and (xxii).	Remove extra space between C6.5(xxi) and (xxii).

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
26	C6.5(xxiiii)	Full stop omitted.	Insert full stop.
22-26	6	Rather than including parts of Appendix A within the text and duplicating the full document as Appendix A, all important points should be included in the text. RCPA's SPIA can then be included as a reference.	There should be an overarching paragraph which states: Laboratories must comply with standards in requesting (SNOMED CT-AU) and reporting (LOINC, UCUM) using the RCPA reference sets as directed by SPIA. In the terminology and codes section there should also be guidelines addressing code integrity. What if the Laboratory sends an incorrect code? What if the Laboratory does not update their code sets regularly and they become out of date?
28	Appendix A	Formatting issues as there are two sections A.	Amend Reporting Terminology and Code to "B".
28 & throughout	B1	Ensure there is consistency of terms between NPAAC, SPIA and HL7.	Amend accordingly and include in definitions.
37	References	Ensure references are current (e.g. SPIA).	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):