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Dear Pathology Stakeholder,

**NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL (NPAAC)
PROPOSED AMENDMENTS TO THE *REQUIREMENTS FOR SUPERVISION IN
THE CLINICAL GOVERNANCE OF MEDICAL PATHOLOGY SERVICES
AND TRANSITION PERIOD***

Since the publication of the *Requirements for Supervision in Clinical Governance (Fourth Edition 2018)*, there have been a number of concerns raised by the pathology sector, including:

- about the role of Clinical Scientists, in the supervision of pathology testing and the recognition of qualifications for Clinical Scientists in Artificial Reproductive Technology (ART) laboratories;
- the exclusion of use of in-house in-vitro diagnostic tests and scope of testing in Category S laboratories;
- what is meant by normal working hours; and
- the proposed implementation date.

NPAAC has given further consideration to the key issues and at its meeting on 11 October 2018, NPAAC endorsed the following proposed amendments in response to the key issues raised by the pathology sector submissions:

- inclusion of additional qualifications criteria for Clinical Scientists, particularly for ART and Bone Marrow Transplant laboratories, in the definition for Clinical Scientist;
- removal of the provision that the Designated Person in a Category S laboratory be “on site”;
- removal of the current statement regarding exclusion of in-house IVDs in Category S laboratories;
- removal of the provision that lists allowed extended tests for Category S ART laboratories;
- removal of the words in the S4.3 “...and for patients of the practice...”;
- inclusion of a definition for normal working hours;
- clarification of supervision arrangements for Category GY and Category B laboratories; and
- clarification of supervision arrangements for leave coverage.

In addition, noting the sector's concerns, NPAAC has recommended the date of effect of the 2018 Supervision Requirements be changed from 1 December 2018 to 1 August 2019. This would extend the transition period by an additional eight months (from the initial proposed date of effect) to provide laboratories more time to make arrangements to meet the revised supervision accreditation requirements.

The NPAAC Secretariat is aiming to expedite the publication of the revised Requirements, undertake the regulatory administrative processes, including amend the Pathology Principles to reflect the NPAAC recommendations at the earliest possible time, subject to approval by the Minister's delegate. It is anticipated that a further communication will be provided when a further status update is available.

NPAAC intends to continue to provide further guidance materials to assist with the understanding of the intent and interpretation of the revised Requirements. Should you have any further queries, please contact the NPAAC Secretariat via Email – npaac@health.gov.au.

Yours sincerely

A handwritten signature in black ink, appearing to read "Beverley Rowbotham". The signature is fluid and cursive, with a large initial 'B' and 'R'.

Associate Professor Beverley Rowbotham
Chair, NPAAC
5 November 2018