Australian Commission on **Safety and Quality** in Health Care

NPAAC
National Pathology Accreditation Advisory Council

National Pathology Accreditation Advisory Council (NPAAC)

Meeting 90 Communiqué

The National Pathology Accreditation Advisory Council (NPAAC) met on 25 May 2026, to consider key reforms and priorities for the National Pathology Accreditation Scheme. The agenda included discussion on the development of the National Pathology Standards (NPS), legislative modernisation, emerging technologies, and future accreditation requirements.

What this Communiqué covers

This Communiqué provides a summary of key discussions, advice and outcomes from NPAAC meetings. Published following each Council meeting, it is intended to improve transparency and keep the pathology sector informed of emerging issues, standards development activities and priorities that may affect pathology accreditation and practice.

Key Outcomes

National Pathology Standards (NPS)

Members reviewed the latest draft of the NPS and provided detailed feedback across a range of areas, including clinical governance, laboratory supervision, genomic testing, communication of results, medical devices and specimen testing requirements.

Key themes from the discussion included:

- ensuring requirements remain practical and achievable across diverse laboratory settings
- supporting workforce flexibility while maintaining patient safety and clinical oversight
- improving clarity around supervision requirements and complex genomic testing
- strengthening interoperability and structured reporting requirements
- ensuring emerging technologies, including artificial intelligence and software-based diagnostics, are appropriately addressed.

NPAAC endorsed the progression of the NPS, subject to agreed amendments being incorporated. The NPS will now proceed through a Regulatory Impact Analysis and the Commission's internal approval processes before broader release for implementation feedback and transition planning.

In Vitro Diagnostic (IVD) Software Requirements

Members considered proposed amendments to strengthen requirements for software used in in-house IVDs, including the introduction of a dedicated standard to support the governance, development and use of software-based diagnostic systems. Discussions focused on ensuring the requirements remain fit-for-purpose as software, artificial intelligence and machine learning technologies become more widely used in pathology practice.

NPAAC endorsed the proposed direction of the amendments. The Commission will review identified areas to ensure requirements are not duplicative or inconsistent before progressing legislative amendments. Subject to approval, a 12-month transition period will support implementation by pathology services.

Information, Communication and Reporting Requirements

Members considered proposed amendments to support the use of contemporary interoperability standards, including HL7 FHIR, and discussed the importance of ensuring the pathology standards framework keeps pace with evolving digital health requirements.

NPAAC endorsed the amendments, which support improved information exchange between pathology services, healthcare providers and national digital health systems, including My Health Record. The amendments came into force in July 2026.

Haemopoietic Cellular Therapy Requirements

Members received an update on the review of requirements for haemopoietic progenitor cell services. Discussions focused on ensuring the revised requirements will align with current international best practice and emerging cellular therapies, including CAR-T and gene-modified cell treatments.

The proposed revisions would:

- broaden scope to include manufactured immune effector cells
- strengthen quality systems and risk management requirements
- introduce updated donor assessment and testing requirements
- include environmental monitoring and accreditation outcomes data requirements
- mandate application of the ISBT 128 labelling standard.

Public consultation commenced in July 2026 and closed on 12 August 2026. The Commission will now review stakeholder feedback and work with the technical working group and NPAAC to finalise the requirements before progressing the next stage of approvals.

Human Genetic Variation Requirements

NPAAC discussed concerns raised by a stakeholder regarding recent amendments to S1.01 of the *Requirements* to specify nurse practitioners and midwives as providers of referrals for medical human genetic testing to accredited laboratories. The stakeholder indicated that inclusion of nurses and midwives as referrers for genetic testing without specifying the tests may lead to inappropriate requesting by nurses and midwives.

The amendment was made in response to a change to the *Health Insurance Regulations 2018* on 1 November 2025, which enabled midwives and nurse practitioners to request specific MBS items 73420 and 73421.

Members agreed that no further amendment to the current wording was required, however the Commission will engage with relevant genetic pathology stakeholders and develop communications to clarify the intent of the existing requirements.

National Pathology Accreditation Scheme Reform

The Council reviewed ongoing work to modernise the National Pathology Accreditation Scheme. Discussion focused on:

- remote and hybrid pathology work practices
- the suitability of the current accreditation framework, where there is no formal connection between the authorities responsible for development of standards and the accrediting agency.
- the timeliness of response when Standards need to respond to changes in practice
- emerging risks associated with digital and distributed pathology services
- opportunities to strengthen quality and safety oversight through future legislative reform.

Members broadly supported continued work in this area and were invited to provide further feedback on risks arising from the current accreditation scheme framework. Feedback from NPAAC and the broader pathology sector will help inform future reform options and priorities.

Legislative Framework Review

NPAAC discussed the challenges of the current legislative framework, which was developed for a very different operating environment and may not adequately support contemporary pathology practice.

Members identified several emerging risks and challenges, including:

- direct-to-consumer testing and home testing kits
- laboratories offering non-MBS human testing
- evolving pathology network models
- digital service delivery and remote supervision
- clinical governance arrangements within large pathology networks
- regulatory gaps affecting consumers and providers.

The Commission will work with the Department to document these issues and inform future policy and legislative considerations. As this work progresses, stakeholders will be provided with opportunities to contribute feedback through consultation and engagement activities.

Assisted Reproductive Technology (ART)

Members were briefed on the Commission's work to develop national standards and an accreditation scheme for Assisted Reproductive Technology services. Discussion focused on the proposed framework and implementation approach.

Public consultation on draft standards remains open until 6 September. Feedback will inform refinement of the standards ahead of a pilot accreditation program expected to commence in 2027.

Emerging Issues

Members discussed emerging safety and quality considerations, including:

- future implications of genomic newborn screening programs
- developments in molecular pathology and solid tumour testing
- ongoing work to clarify the role of clinical scientists within pathology services.

These discussions will help inform future standards development, accreditation reform activities and policy advice provided by NPAAC.

NPAAC meetings provide an important forum for expert advice on pathology standards, accreditation and emerging sector issues. Through these communiqués, the Commission will continue to share key outcomes and future work priorities following each biannual meeting to support greater transparency and awareness across the pathology sector.

Next Steps

Over the coming months, the Commission will:

- finalise and progress the NPS
- undertake consultation on revised Haemopoietic Cellular Therapy requirements
- continue work on legislative and accreditation reform priorities
- engage stakeholders on genetic pathology and remote working issues
- progress amendments supporting contemporary digital health interoperability and in house IVD software requirements.

The next NPAAC meeting will be held in October 2026.