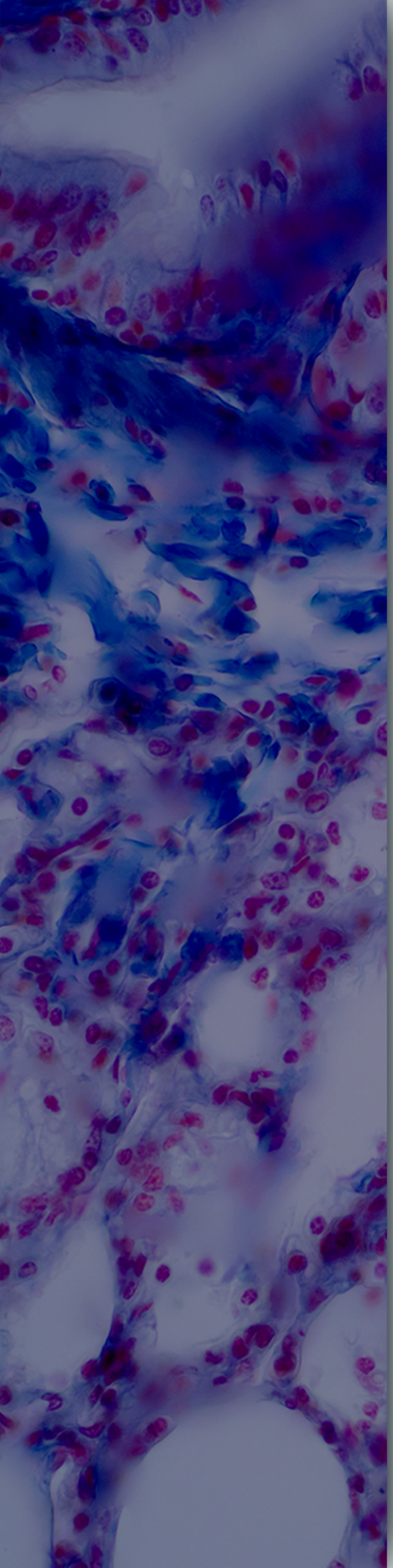
NATA explains

Australia's legislation and quality infrastructure for

Human Pathology

NATA DELIVERING CONFIDENCE for more than 75 years

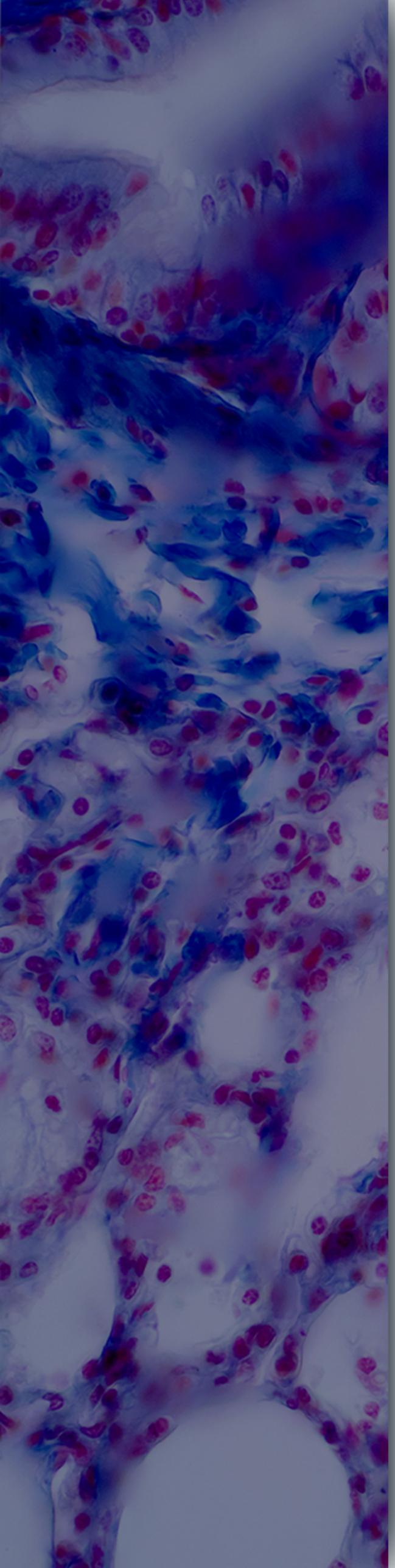


Human Pathology

Human pathology in Australia has one of the most rigorous frameworks for the maintenance of quality and patient safety in the world. This results from the high standard of pathologist and medical scientist training together with a supporting standards and conformance infrastructure that is mature and comprehensive.

What is this standards and conformance infrastructure (SCI)?

It begins with the four organisations underpinning a vast range of manufacturing and service delivery activities in our economy that are collectively recognised by the Australian Government as Australia's standards and conformance infrastructure.



These four bodies are also Australia's members of the international organisations overseeing these activities globally

National Measurement Institute, Australia (NMI)

NMI develops and maintains the nation's measurement systems under the National Measurement Act. As such, it is the national authority for physical, chemical and biological metrology and is part of the Department of Industry, Science and Resources.

Standards Australia

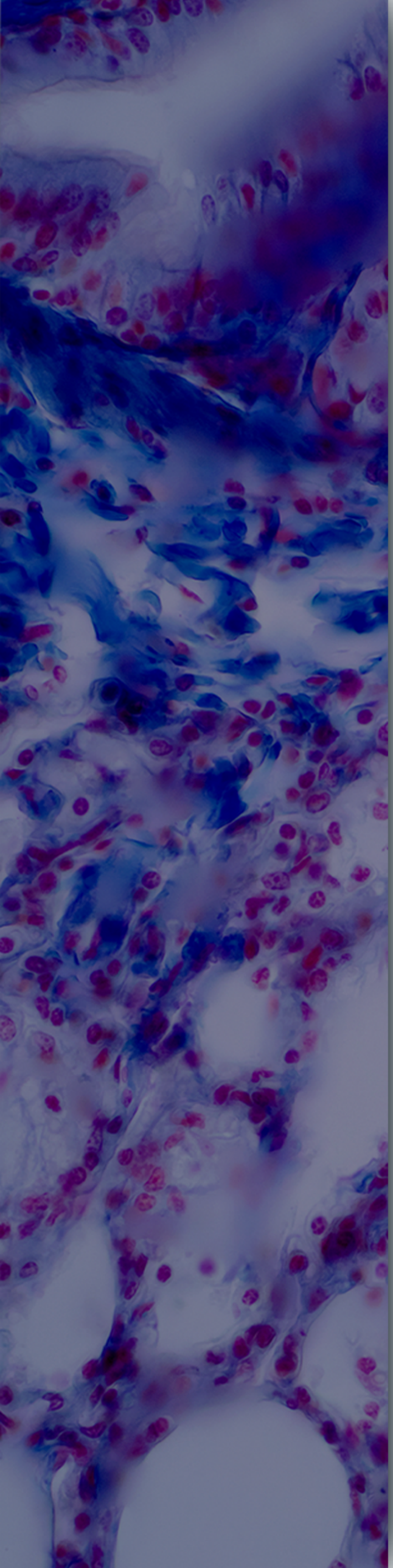
Standards Australia produces the documentary standards used in commerce and industry. It is the peak body responsible for producing standards and also for accrediting sector-specific standards development organisations.

National Association of Testing Authorities (NATA)

NATA accredits laboratories, proficiency testing providers, biobanking, reference material producers and inspection bodies. Accreditation is based on demonstrated competence and capability of bodies to determine conformity with requirements (typically standards).

Joint Accreditation System of Australia and New Zealand (JASANZ)

JASANZ accredits certification bodies and inspection bodies to determine the conformity of products and services with requirements (typically standards).



In the case of human pathology, there are additional key contributors to the standards and conformance infrastructure that underpin the very high quality of services available in Australia.

Royal Australasian College of Pathologists (RCPA)

As the professional college for pathologists, the RCPA is a primary source of expertise on the practice of pathology and, as such, is both:

- A joint partner in the NATA/RCPA accreditation program for human pathology laboratories;
- Highly active on committees writing the standards for pathology

Commonwealth Department of Health and Aged Care (Health)

Health has responsibility for the policy, regulation and legislation relating to the payment of Medicare benefits for pathology services and the National Pathology Accreditation Scheme (NPAS).
NPAS is a compulsory accreditation system for pathology laboratories. Commencing in 1986, the NPAS requires a pathology laboratory to meet specified quality standards for their services to be eligible for Medicare benefits.

With the exception of some basic tests conducted by some medical practitioners within their own medical practice, Medicare benefits for pathology services are only payable if:

- they are clinically relevant and requested by a doctor or health professional; and
- provided by or on behalf of an approved pathology practitioner, in an accredited pathology laboratory operated by an approved pathology authority.

Medicare subsidises the costs of pathology services listed in the Medicare Benefits Schedule (MBS).
Pathology services eligible for Medicare benefits are listed in the Pathology Services Table (Category 6) of the MBS.

Services Australia

Services Australia has responsibility for the payment of Medicare benefits and the approval of Accredited Pathology Laboratory (APL) premises under the Act. For a Medicare benefit to be payable, the pathology service must be performed in an APL that is approved for that service by Services Australia on the date of the service being performed.

Services Australia process APL applications (including the payment of fees), renewal of APL approvals, variations of approval and, for laboratory closures or those that fail to meet the accreditation requirements, revocations of APL approvals.

Approved Pathology Authorities that own APLs must inform Services Australia within 14 days of any changes to information provided, including changes to premises and scope of testing. APL approvals are location specific and cannot be transferred.

Therapeutic Goods Administration (TGA)

The TGA (as Australia's regulatory authority under the Department of Health and Aged Care) has an important role in the quality of pathology services through the regulation of in vitro diagnostic medical devices (IVD) used in laboratories. Listing on the Australian Register of Therapeutic Goods (ARTG) provides a means for pathology practitioners to identify IVDs that are legally approved for use.

The TGA also regulates laboratory use of in-house developed IVDs.

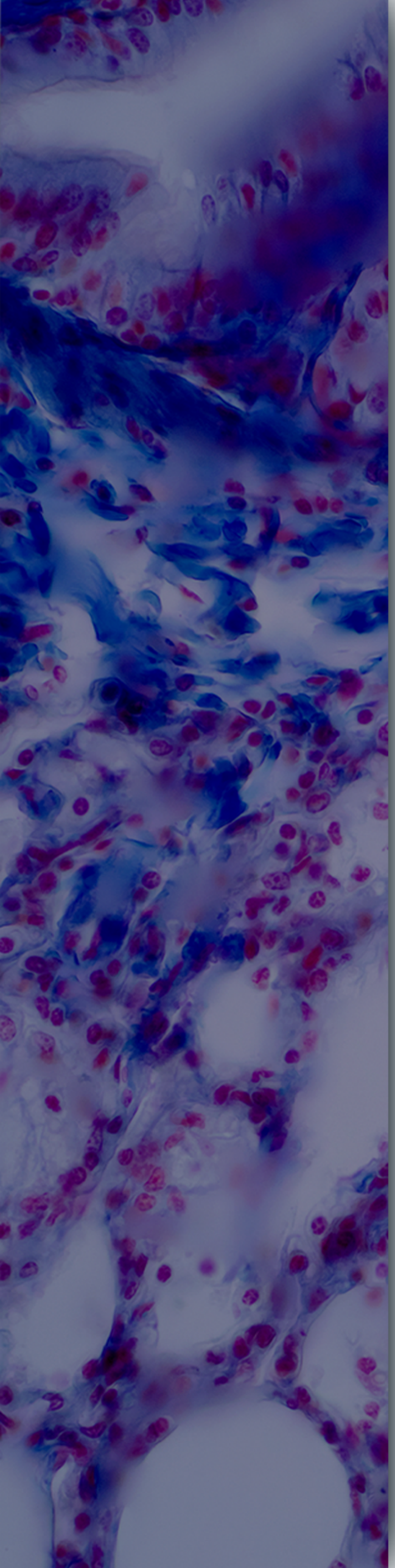
Australian Commission on Safety and Quality for Healthcare (The Commission)

The Commission has responsibility for the operation of NPAAC and the production and maintenance of NPAAC standards. The Commission also has administrative responsibility for the accreditation process defined by the Principles.

National Pathology Accreditation Advisory Council (NPAAC)

NPAAC is a ministerially-appointed Council established in 1979 with responsibilities that include the development and maintenance of standards for human pathology used as accreditation criteria for pathology laboratories in Australia.

Standards are developed with input from relevant stakeholders to ensure that there is balance between their needs. Stakeholders include pathologists, scientists, patient advocates, clinicians and government.



How the Medicare benefits legislation relates to pathology

Health is responsible for the following legislation related to pathology accreditation:

Health Insurance Act 1973 (the Act)

The Act provides for the payment of Medicare benefits, including benefits for pathology services.

Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017 (the Principles)

The Principles approved under section 23DNA of the Act operate to ensure that appropriate standards are met and maintained in pathology laboratories where Medicare eligible pathology services are provided. The Principles include a Schedule that lists the pathology accreditation standards that must be met for each category of laboratory and the kinds of services provided in those laboratories. The accreditation material is developed and maintained by the National Pathology Accreditation Advisory Council.

Health Insurance (Approvals for Eligible Collection Centres) Principles 2020

In order for Medicare benefits to be payable for pathology services rendered, pathology specimens must be collected at an approved collection centre (ACC), or at another type of location specified in subsection 16A (5AA) of the Health Insurance Act 1973. This legislative instrument is approved under Subsection 23DNBA (4) of the Act and sets out the principles to be applied in granting approvals for eligible pathology specimen collection centres under subsection 23DNBA (1) of the Act. It prescribes the prerequisites for the granting of approvals for ACCs, notice requirements and the duration of approval.

Health Insurance (Approved Pathology Undertakings) Approval 2017

This legislative instrument sets out obligations on Approved Pathology Practitioners (APP) and Approved Pathology Authorities (APA) that ensure they are accountable for pathology services that are rendered by or on their behalf in an accredited pathology laboratory and with respect to their eligibility for Medicare benefits for pathology services. The overarching objective of the approved forms of undertaking for APPs and APAs is to ensure patient safety in the provision of pathology services.

Health Insurance (Pathology) (Fees) Act 1991

This Act identifies the fees payable to the Australian Government, as represented by Services Australia, associated with applications for the acceptance of an approved pathology practitioner undertaking, an approved pathology authority undertaking, or approval of premises as an accredited pathology laboratory under subsections 23DC(1), 23DF(1) and 23DN of the Act respectively.

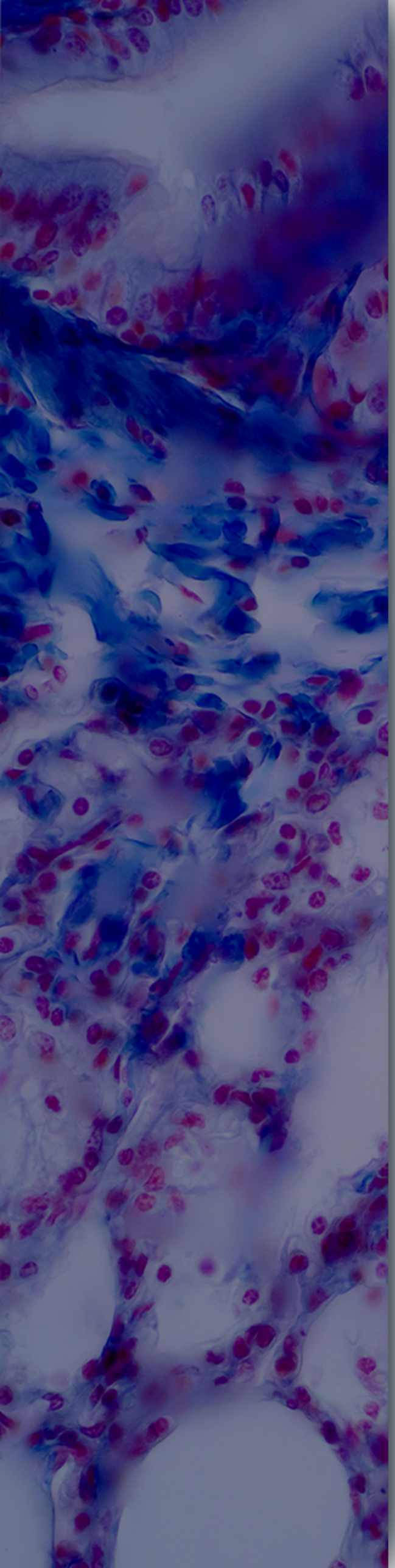
Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000

This Act identifies the tax imposed by the Australian Government on the grant of an approval for a specimen collection centre under the Act.

How accreditation and approval work in practice

When a pathology laboratory wishes to be eligible for any pathology services listed on the Medical Benefits Schedule, the Act requires it to be approved by the Minister as an Accredited Pathology Laboratory.

To be approved, the Principles require that the laboratory meet all of the relevant NPAAC standards that are prescribed and that this be demonstrated through an assessment by an ‘independent body’ - which is NATA. In addition to those described in the Principles, NATA’s obligations are detailed in a Deed with Services Australia and the Department of Health and Aged Care.



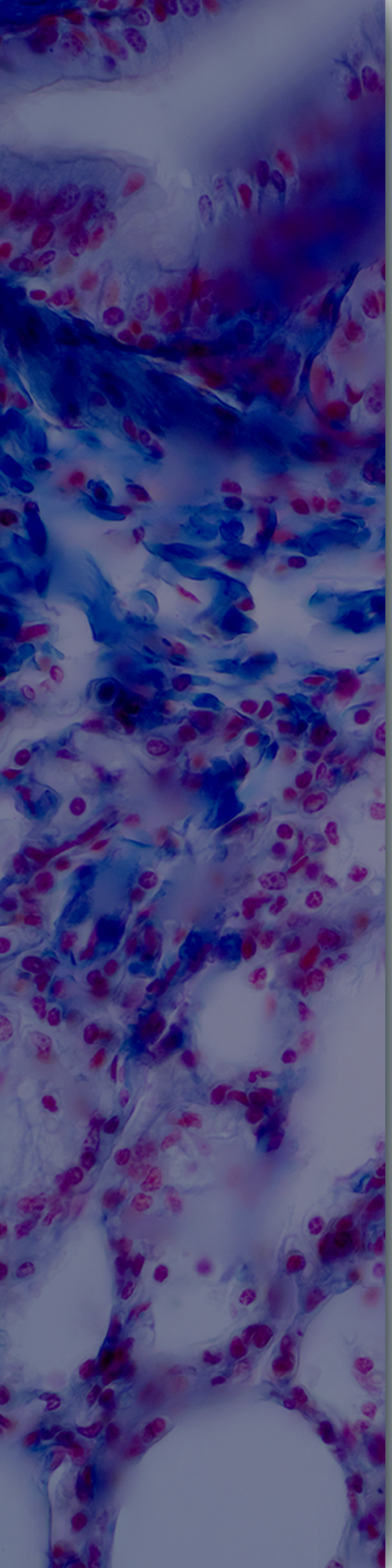
1 Advisory Phase

- The pathology laboratory requests NATA to conduct an on-site advisory visit under the joint NATA/ RCPA human pathology accreditation program.
- Relevant documentation is provided to NATA to facilitate preparation for the visit.
- The visit is conducted to confirm there is an appropriately equipped pathology laboratory at the premises and to assess the readiness of the laboratory to provide pathology services in accordance with relevant NPAAC standards prescribed by the Principles.
- If the laboratory is at an appropriate state of readiness, an application for NATA/RCPA accreditation is lodged with NATA.
- NATA issues an Advisory Report to the laboratory which confirms the findings from the visit and states the groups of MBS pathology services for which the laboratory seeks approval.

2 Initial APL Approval

- The laboratory lodges an application for approval as an APL to Services Australia together with latest Advisory Report issued by NATA.
- If the application is approved in principle Services Australia will request the accreditation fee. When the fee is received, it approves the laboratory as an APL for a period not exceeding six months, effective from the date of the Services Australia delegate's decision.

It should be noted that, at this stage of the process, the laboratory does not hold NATA/RCPA accreditation



3 Assessment phase

- The laboratory will advise NATA of its readiness for an initial assessment.
- NATA conducts the initial assessment of the laboratory as soon as practical. This is a peer assessment process that will include a NATA lead assessor and - depending on the category of laboratory and the range of disciplines undertaken - pathologists and scientists having the requisite expertise to evaluate the laboratory's compliance with the relevant NPAAC standards as listed in Schedule 1 of the current version of the Principles as well as ISO 15189.
- At the conclusion of the assessment, NATA issues a report of its findings which includes any non-complances with accreditation requirements.
- The laboratory submits its response to the assessment findings explaining the actions taken to address non-compliances together with appropriate evidence.
- Once the laboratory has demonstrated that all non-compliances have been addressed, NATA will seek a recommendation from NATA's Human Pathology Accreditation Advisory Committee and proceed with granting the NATA/RCPA accreditation.
- Upon accreditation, NATA will issue the laboratory with a Certificate of Accreditation together with a Scope of Accreditation which describes the tests for which accreditation is held. The Scope may include tests that are not listed on the MBS.
- NATA will also issue an Assessment Report to the NATA/RCPA accredited laboratory stating that the laboratory complies with the relevant NPAAC standards. The Assessment Report will include the groups of pathology services from the MBS for which NATA/RCPA accreditation has been granted and a period of up to 3 years for which the laboratory can be expected to meet the relevant standards for the purposes of eligibility to Medicare benefits. Services not listed on the MBS are not included on the Assessment Report even if covered by NATA/RCPA accreditation.

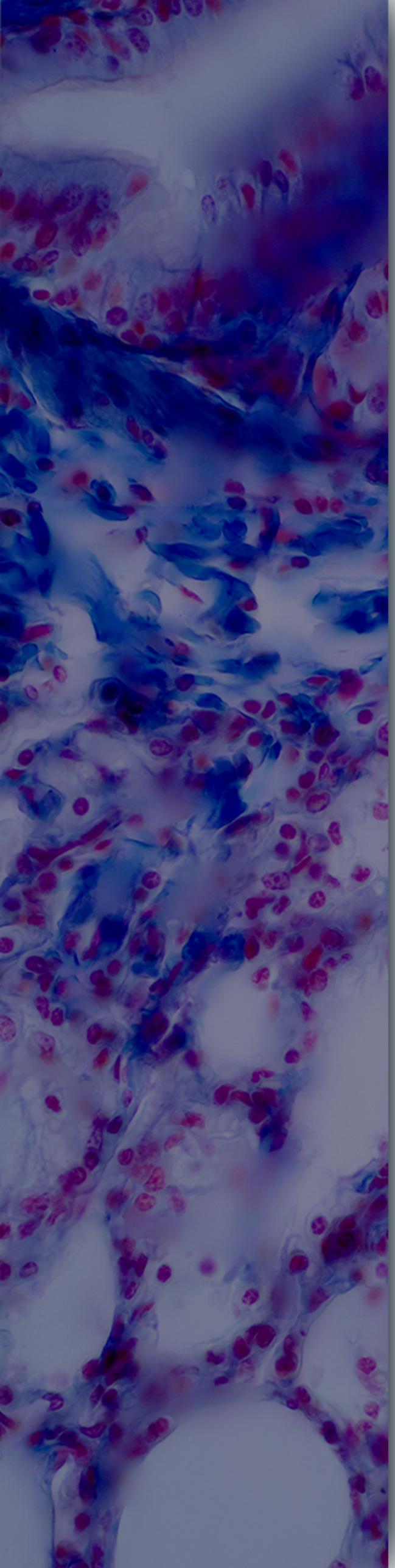
4 APL Approval

- The laboratory lodges an application to renew their approval as an APL to Services Australia together with latest Assessment Report issued by NATA.
- If the application is approved in principle, Services Australia approves the laboratory as an APL for a period no longer than the period recommended by NATA in the Assessment Report. This approval must be granted no more than one month after the initial Medicare approval expires in order to maintain continuous Medicare accreditation. For this reason, APL renewal applications need to be submitted allowing
adequate time for processing. Processing times will vary depending on the priorities and workload of Services Australia at the time.

  APL renewals cannot be backdated to include additional groups of pathology services.

5 Ongoing cycle

- Laboratories are subject to ongoing peer reassessments by NATA to maintain their NATA/RCPA accreditation and APL status.



Process considerations

It is important to recognise that, while parts of the process required by legislation are inter-related, they are also independent.

Policy, APL Approval and Funding

Health sets the overarching requirements to safeguard patient safety and government revenues. They are not directly involved in the NATA/RCPA accreditation process but have responsibility for the legislative requirements for the Minister approving APLs.

Standards Development

Standards provide a description of the processes and practices that must be undertaken consistently to deliver reliable and safe outcomes. They should also address the minimum requirements necessary for reliable and fit-for-purpose outcomes rather than what is required for perfection.

The production of standards suitable for pathology practice and related services is not a function of either regulation or accreditation. Pathology standards are produced from knowledge gained from working laboratories and clinicians.

Regulators and accreditation practitioners have legitimate interests in terms of - respectively - achieving regulatory objectives and that requirements can be meaningfully assessed but, in this context, the primary objective of any standardisation process must be to deliver good patient outcomes.

Application of Standards

NATA is bound by the legislation and its contractual arrangements with the Commonwealth to apply the NPAAC standards listed in Schedule 1 of the Principles. From time to time, new NPAAC Standards or editions thereof will be added and old versions repealed. NATA must apply the new or amended standards:

- from the date of publication of amendment to the Principles on the www.legislation.gov.au website; or
- in accordance with any transitional arrangements included in the Principles.

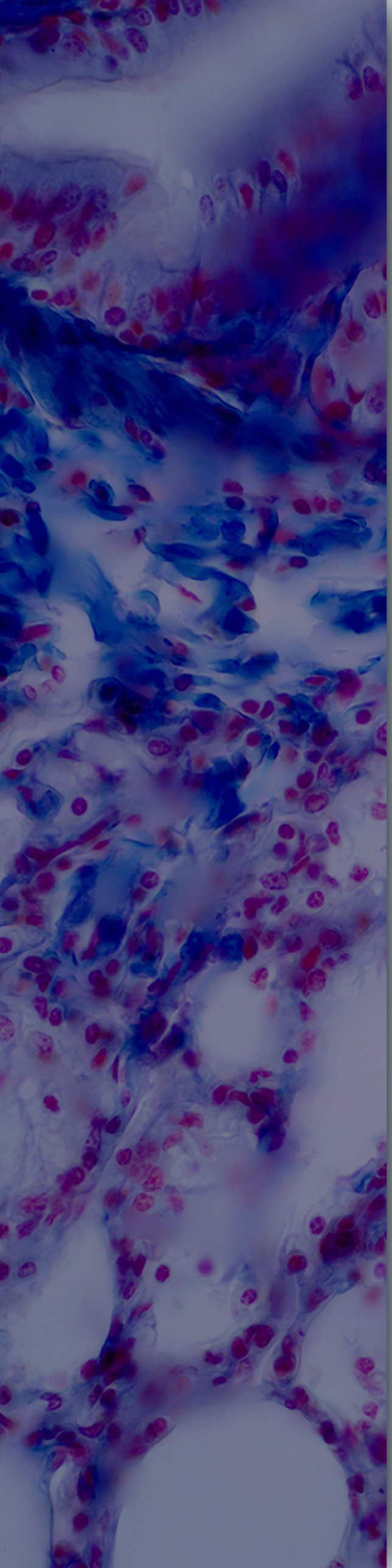
Accreditation

It is well understood within government and accreditation systems that:

- standards are voluntary until mandated in legislation or a code; and
- the existence of a standard does not lead to satisfactory outcomes until it is consistently and competently applied to its intended purpose.

As practiced by NATA - accreditation is about ascertaining and recognising a pathology laboratory's collective competence, capability and consistent compliance with fit-for-purpose standards. As such, standards form part of the accreditation criteria and are a tool used in the assessment process. As stressed above, NATA does not write standards but is responsible for other criteria around the mechanics of accreditation such as the laboratory's responsibilities for:

- fee payment;
- making staff and facilities available for peer assessment;
- timely provision of responses to assessment findings;
- use of the NATA and RCPA logos on reports and in promotional material.



NATA does develop policies and guidance around such things as laboratory participation in proficiency testing (QAP), instrument calibration and general aspects of laboratory practice that are necessary for reliable outcomes but which may not be addressed in detail by the standards.

As well as using peer assessors to conduct laboratory assessments, NATA seeks advice on technical matters arising at assessments from Fellows of the RCPA and experienced medical scientists who sit on NATA's Human Pathology Accreditation Advisory Committee.

The RCPA also provides NATA with critical advice and guidance on matters relating to peer assessors, professional practice, qualifications (scope of practice) and new technologies.

Accreditation Decisions and APL Status

One very important point is that NATA must make accreditation decisions impartially and independently. While NATA may receive information regarding a particular laboratory from a variety of sources and advice from professional bodies, accreditation decisions are solely NATA's to make based on the evidence gained from the accreditation process.

Except under exceptional circumstances, a laboratory cannot be approved as an APL unless Services Australia has been provided with either an Advisory Report or an Assessment Report issued by NATA. This cannot happen while there are unresolved findings from either the advisory or assessment activity. Services Australia is responsible for making decisions for APLs and their eligibility for Medicare benefits, not NATA.

Laboratory responsibilities under the TGA's IVD framework

Laboratories have legal obligations for 'in-house IVDs' if they:

- modify a commercially supplied Class 1-3 IVD that is included in the ARTG,
- use it outside of its specified intended purpose (as stated in the labelling) or
- develop their own IVD from first principles

Laboratories must evaluate all 'in-house IVDs' under their NATA/RCPA accreditation according to ISO 15189 and the NPAAC standard for in-house IVDs. The requirements for in-house IVDs, including the notification of all in-house IVDs to the TGA, are set out in Schedule 3, Part 6A of the Therapeutic Goods (Medical Devices) Regulations 2002.
If a laboratory imports a Class 1-3 IVD for itself or develops a Class 4 in-house IVD for use within their laboratory, it must be included in the ARTG before it can be imported or supplied (i.e., used), unless otherwise exempt.

How other organisations contribute

- Advisory Committee (HPAAC) which provides advice and recommendations on assessors, assessment findings and
- accreditation decisions. Fellows also act as voluntary peer assessors for NATA's on-site laboratory assessment activities.

- Wherever possible and appropriate, a laboratory will have its instruments calibrated in such a way that there is measurement (metrological) traceability to either SI units or reference materials. Hence, the importance of National Measurement Institute's role.

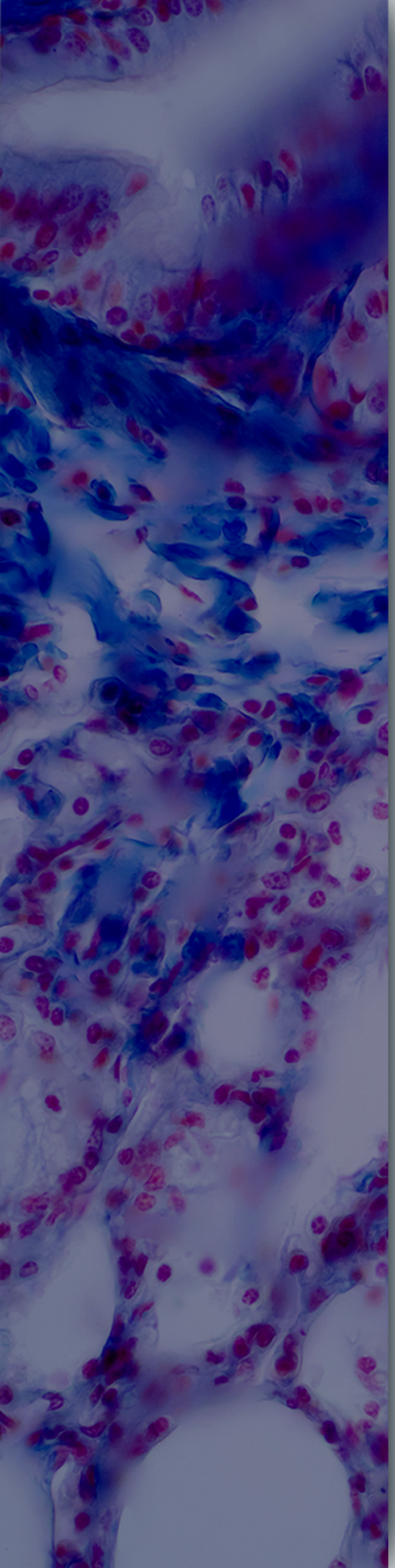
- Standards Australia is responsible for the adoption of ISO 15189 as an Australian Standard. In addition, a broad range of Australian Standards are also important to the safe and effective operation of pathology laboratories. These include the standards for laboratory safety (AS/NZS 2243 series), biological safety cabinets (AS 2252.2), blood refrigerators (AS 3864.1) and similar.

- If laboratories use contractors for various services, it is good practice to use those having their management systems certified for compliance with ISO 9001 Quality Management Systems and/or their personnel certified under a relevant scheme as a means of providing confidence in their services. The certification body will in all likelihood be accredited by JAS-ANZ for compliance with ISO 17021 (management) or ISO 17024 (personnel).

- As well as producing the NPAAC standards, NPAAC under the management of the Commission provides interpretation of NPAAC standards where a laboratory (or NATA in the course of an assessment) identifies a structural or operational process which does not clearly fit the expectations of a particular requirement. For Example: interpretations may be needed to address technological developments and innovative process that achieve a suitable outcome but are not fully accommodated by the standard.

In conclusion

All of the organisations mentioned in this overview have important parts to play in the oversight and delivery of pathology services that meet the needs of the Australian public. All are important yet none can do everything. Australian pathology is as good as it is because of the cooperative and collaborative contributions over many years.



Finding more information

More information on the organisations identified is available at the following locations:

- ACSQHC and NPAAC - https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards
- JASANZ - https://www.jasanz.org
- NATA - https://www.nata.com.au
- NMI - https://www.industry.gov.au/strategies-for-the-future/national-measurement-institute
- RCPA - https://www.rcpa.edu.au
- Services Australia – https://servicesaustralia.gov.au/medicarepathology
- Standards Australia - https://www.standards.org.au
- TGA - https://www.tga.gov.au/ivd-medical-devices-regulation-basics