OFFICE OF REGULATION REVIEW
REQUEST TO ASSESS NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL (NPAAC) ACCREDITATION DOCUMENTS FOR REGULATION IMPACT STATEMENTS

The documents are:

- *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)*
- *National Association of Testing Authorities (NATA) ATA AS 4633 (ISO 15189) Application Document* – Supplementary Requirements for Accreditation in the Field of Medical Testing
- *Requirements for Gynaecological (Cervical) Cytology*
- *Guidelines for the Performance of the Pathology Surgical Cut-Up*

Background on accreditation arrangements

Apart from some basic tests conducted by medical practitioners, Medicare benefits are not payable in respect of pathology services, unless those services are rendered in an accredited pathology laboratory. The accreditation principles, determined by the Minister for Health and Ageing under section 23 DNA of the *Health Insurance Act 1973* are in place to ensure minimum acceptable standards in pathology laboratories. Medicare Australia administers the accreditation process.

Objectives

The main objective of accreditation is to ensure that pathology laboratories perform to best practice guidelines to enable the competent undertaking of specific testing.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to laboratories and accrediting agencies as to the minimum standards considered acceptable for good laboratory practice. Failure to meet these minimum standards may pose a risk to public health and patient safety.

The NPAAC documents may also apply to pathology laboratories seeking accreditation outside of the Medicare benefits arrangements.

Legislation

Both new and revised documents require amendments to Schedule 1 Part 1 of the *Health Insurance (Accredited Pathology Laboratories) - Approval Principles 2002*. Schedule 1 lists the NPAAC documents used by the approved accreditation authorities that assess pathology laboratories seeking accreditation. The Principles are determined by the Minister for Health and Ageing under Section 23DNA of the *Health Insurance Act 1973*.

Consultation

As part of the established NPAAC public consultation process all documents prepared by NPAAC are circulated to:

- All laboratories within Australia
- NPAAC members
- Jurisdictional members
- Members of industry

These documents represent best pathology laboratory industry practice, and the extensive circulation of these documents allowed for comprehensive public comments.

Implementation

To facilitate the implementation of these documents, consideration has been given to the 'Effective date', this allows for industry to make the necessary changes/amendments required by the updated standards/guidelines. The industry has been informed of the proposed changes in the public consultation process when copies of the documents were circulated extensively. Further details of the amendments to the documents are provided in the attachments.

Adherence to these standards is monitored through the established pathology laboratory accreditation process. This consists of inspection and assessment by the National Association of Testing Authorities and the Royal College of Pathologists of Australasia joint accreditation program.

The documents are subject to review by NPAAC every two to three years. These reviews are part of the regular ongoing process undertaken to ensure that they reflect current best pathology laboratory practice.

NEW NPAAC DOCUMENT

1. *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)*

Human immunodeficiency virus (HIV) serology testing was included on the Medicare Benefits Schedule on 1 November 2005. It is proposed that, in order to be eligible for Medicare benefits for this item, laboratories are required to be accredited.

Prior to this testing being listed on 1 November 2005, the HIV and HCV tests were the responsibilities of States and Territories and did not attract Medicare benefits. Now that Medicare benefits are payable and given the sensitivity of these types of testing, it is proposed that these issues are clearly articulated and that specific guidelines are available.

These NPAAC standards are intended to apply to all pathology laboratories testing for antibodies to HIV or HCV, irrespective of Medicare benefit. It is also intended that these standards will apply to public laboratories that are conducting these tests from their own funds.

HIV and HCV are generally regarded as 'infections of special public health significance' and, as such, laboratory testing for these viruses is regulated at a higher level than for most other diagnostic tests. Notwithstanding the special public health significance of the infections caused by HIV and HCV, the serology testing process is similar to other routine immunoassays.

These standards have been developed with reference to current Australian and other international standards including:

- NPAAC *Standards for Pathology Laboratories*
- NPAAC *Guidelines for Quality Systems in Medical Laboratories*
- ISO 15189.2003 *Medical Laboratories — Particular Requirements for Quality and Competence.*

Impact of new guidelines

Parties mostly affected by the new guidelines are:

- pathology industry (public and private)
- government
- consumers

Many pathology laboratories have been for some time testing for HIV and HCV and are already meeting the required minium standards. However, there are many laboratories that have not had experience in this type of testing and clear guidance would be of assistance. In introducing the new guidelines minimal changes and costs could occur in relation to improved staffing arrangements or additional staff training. These guidelines will bring the testing into line with international best practice.

Benefits

The benefits to the pathology industry are:

- the operation of standards and guidelines provide clear guidance to enable pathology services to be performed to a consistent quality and to meet international best practice
- to provide clear guidance in tests results are generated and confidential
- the risk of potential litigation is reduced.

The benefits to the government are:

- that minimum standards will provide confidence that tests are conducted in accordance with best practice and will provide reliable diagnostic information for treating practitioners
- the use of these guidelines will result in reliable diagnostic information
- the need for repeat tests is minimised through clear guidance to the laboratory on the required standards i.e. multiple paying against Medicare for poor testing.

Implications of not introducing the new guidelines

- confidentiality and privacy of patients could be put at risk
- no consistency of testing
- no safety guidelines to conduct these types of tests
- number of pathology laboratories that have not previously conducted these tests could now be required to perform this function, with no guidance
- obtaining uniformity and reliability of results will be difficult to achieve.

REVISED NPAAC DOCUMENTS

1) *Guidelines for the Performance of the Pathology Surgical Cut-Up*

This document provides standards and guidance on good laboratory practice in relation to Surgical Cut Up. It also provides a detailed framework for assessors carrying out laboratory accreditation assessments.

The document was first published in 2001.

Summary of changes

- Format restructured to include standards and commentaries
  - the standard is derived from the current wording for each section already contained in the document
  - new titles/headings have been included for each section to identify the standard
- Definitions for scientist, senior scientist and specialist pathologist included in definitions in line with other NPAAC documents and in accordance with definitions in the *Health Insurance Act 1973*
- General update of content in line with current pathology practice.

Impact of changes

- Minor changes that relate to formatting, definitions and consistency with other NPAAC documents.

2) *Requirements for Gynaecological (Cervical) Cytology*

This document has been prepared for laboratory directors to assist them achieve the standards of practice adopted by NPAAC in relation to the operation of gynaecological cytology services and must be read in conjunction with other NPAAC documents.

The document was first published in 2004.

Summary of changes

States and Territories have previously recorded results in a variety of ways; these guidelines will specify how results are to be reported consistently across Australia, therefore allowing various jurisdictional cancer registries to manage data from test results in a uniform manner. Pathology laboratories will also be required to report test results in accordance with NHMRC guidelines. Industry has been consulted regarding these changes and most laboratories will be able to adapt to these changes with ease.

- Format restructured to include:
  - references
  - appendix A and B
  - an Introduction, consistent with other NPAAC documents
- Some standards have been expanded to be consistent with NHMRC guidelines
- General update of content in line with current pathology practice.

Impact of changes

Many laboratories have worked previously or had links with State Cancer Registries and/or women's health programs. This has resulted in numerous interpretations of results. These amended standards will result in the changing of reporting requirements and will enable results to be reported in a uniform and consistent manner.

It has been reported by the industry that these amendments will not adversely affect the outcomes for most laboratories. State and Territory based cancer registries are already in the process of amending their databases to accommodate these changes, which will greatly assist the national management of cervical screening.

3) ***New National Association of Testing Authorities ATA AS 4633 (ISO 15189) Application Document* – Supplementary Requirements for Accreditation in the Field of Medical Testing**

ISO 15189 is the updated International Standard ISO 17025.

This NATA field application contains specific information from ISO 15189 that relate to pathology laboratories testing (the previous field application was drafted against the old version of this standard). This NATA field document sits under the AS 4633 (ISO 15189) Standard. It provides further explanation of clauses in the Standard and details additional technical and specific requirements with which laboratories must comply.

The document was first published in 2005.

Summary of Changes

- Format restructured to include:
  - current definitions
  - reference list
  - amended guidelines for pretransfusion testing
  - removal of duplication
- Extensive re-formatting to Section 3
- Laboratories requirements for mandatory documentation for accreditation
- Advice concerning the suspension and cancellation of accreditation
- General update of content in line with current pathology practice and international standards

Impact of Changes

- There is minimal impact on the industry as this document provides information on the accreditation process as well as detailing specific technical requirements for laboratories, which have been previously reviewed through NATA's technical consultative channels.
- This document will give consistent guidelines to field assessors to help measure laboratories against international standards.