



Health Insurance (Accredited Pathology Laboratories — Approval) Amendment Principles 2007 (No. 1)

Health Insurance Act 1973

I, ANTONY CHARLES KINGDON, Acting First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, determine these Principles under subsection 23DNA (1) of the *Health Insurance Act 1973*.

Dated 22 January 2007

ANTONY KINGDON
Acting First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing

1 Name of Principles

These Principles are the *Health Insurance (Accredited Pathology Laboratories — Approval) Amendment Principles 2007 (No. 1)*.

2 Commencement

These Principles commence on 1 July 2007.

3 Amendment of *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002*

Schedule 1 amends the *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002*.

Schedule 1 Amendments

(section 3)

- [1] **Subsection 5 (1), definition of *accreditation materials***
substitute
accreditation materials means each document mentioned in Schedule 1, published in the year mentioned for the document.
- [2] **Subparagraph 11 (1) (a) (ii)**
omit
for
- [3] **Paragraph 11 (4) (b)**
omit
for
- [4] **Paragraph 12 (3) (a)**
before
a representative
insert
that
- [5] **Paragraphs 12 (3) (b) and (c)**
before
the independent body
insert
that
- [6] **Paragraph 12 (3) (c)**
omit
confidence
insert
confidence,

[7] Subparagraph 12 (3) (c) (ii)*substitute*

- (ii) the premises are, or will be, appropriately staffed with persons to carry out, and persons to direct, control and supervise, the pathology services to be performed at the premises; and

[8] Paragraph 15 (1) (a)*omit*

covered by the approval,

insert

covered by the approval

[9] Schedule 1*substitute***Schedule 1 Accreditation materials**

(section 5)

Part 1 NPAAC materials

Item	Material	Publication year
1	Guidelines for Data Communication	1998
2	Information on the Transport of Pathology Specimens	1998
3	Guidelines for Cytogenetics Laboratories	2001
4	Retention of Laboratory Records and Diagnostic Material	2002
5	Guidelines for Laboratory Procedures Related to the Processing, Storage and Infusion of Cells for Transplantation or Cell Therapy	2004
6	Guidelines for the Facilities and Operation of Hospital and Forensic Mortuaries	2004
7	Standards for Pathology Laboratory Participation in External Proficiency Testing Programs	2004
8	Guidelines for Approved Pathology Collection Centres	2006
9	Guidelines for the Performance of the Pathology Surgical Cut-up	2006
10	Guidelines for the use of Liquid Based Collection Systems and Semi-Automated Screening Devices in the Practice of Gynaecological (Cervical) Cytology	2006
11	Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis	2006

Item	Material	Publication year
12	Performance Measures for Australian Laboratories Reporting Cervical Cytology	2006
13	Requirements for Gynaecological (Cervical) Cytology	2006
14	Requirements for Supervision of Pathology Laboratories	2006
15	Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and the Hepatitis C Virus (HCV)	2006
16	Guidelines for Quality Management in Medical Laboratories	2007
17	Requirements for Pathology Laboratories	2007
18	Requirements for the Development and Use of In-house In Vitro Diagnostic Devices (IVDs)	2007
19	Requirements for the Estimation of Measurement Uncertainty	2007

Note The documents mentioned in Part 1 are available on the Internet — see www.health.gov.au/npaac.

Part 2 Other materials

1. National Association of Testing Authorities NATA AS 4633 (ISO 15189) Application Document — Supplementary Requirements for Accreditation in the Field of Medical Testing, published in 2005.

Note The document mentioned in item 1 is available from the National Association of Testing Authorities — see www.nata.asn.au.