



Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002

HS/11/2002

I, KAY CHRISTINE LESLEY PATTERSON, Minister for Health and Ageing, make the following Determination under subsection 23DNA(1) of the *Health Insurance Act 1973*.

Dated 13th November 2002

Kay Patterson

Minister for Health and Ageing

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Part 1 Introductory

1 **Name of Principles**

These Principles are the *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002*.

2 **Commencement**

These Principles commence on 1 January 2003.

3 **Application of Principles**

These Principles apply to the exercise by the Minister of a power under section 23DN of the Act after commencement in relation to:

- (a) an application for approval of premises as an accredited pathology laboratory whether that application was made before or after commencement; and
- (b) the exercise by the Minister of a power to revoke or vary an approval of premises whether the approval was given before or after commencement.

Note See the terms of subsection 23DN (3) of the Act — “The Minister shall, in exercising the Minister’s powers under this section at a particular time, apply the principles determined under section 23DNA that are in force at that time.”.

4 **Revocation of previous Principles**

All Principles previously determined under subsection 23DNA (1) of the Act are revoked.

5 **Interpretation**

- (1) In these Principles:

accreditation action means an independent body’s grant, refusal to grant or revocation of accreditation, however any of these actions are described, in relation to the provision of some or all of the pathology services provided at premises.

accreditation materials means the materials referred to in Schedule 1.

Act means the *Health Insurance Act 1973*.

advisory report means a report provided by an independent body in accordance with subsection 12 (3).

assessment report means a report provided by an independent body or a special adviser in accordance with section 9.

category means a category under section 17.

independent body means:

- (a) NATA; and
- (b) in relation to a category M laboratory — any other organisation approved under subsection (2) by the Minister.

NATA means the National Association of Testing Authorities Australia (ACN 004 379 748) being the body recognised by the Commonwealth through a Memorandum of Understanding as the national body in Australia for laboratory accreditation.

NPAAC means the National Pathology Accreditation Advisory Council established under subsection 9 (1) of the *National Health Act 1953*.

premises means premises or a part of any premises used or proposed to be used as a pathology laboratory.

relevant standards means standards set out in the accreditation materials and in relevant requirements of these Principles including sections 17 and 18.

special adviser means a person appointed by the Minister to advise the Minister on the standards of pathology services provided at premises.

State includes a Territory.

State accreditation means accreditation under an accreditation system under the written law of a State or under a State Government administrative arrangement to provide accreditation, however described, for provision of pathology services.

undertaking means an undertaking given under section 23DC or section 23DF of the Act.

- (2) Subject to subsection (3), the Minister may approve an organisation as an independent body in relation to a category M laboratory for the purposes of these Principles.
- (3) In making a decision under subsection (2) the Minister must take into account that:
 - (a) ordinarily an organisation other than NATA should only be approved if there is a high level of confidence that the body is a suitable body to act as an independent body for the purposes of these Principles; and
 - (b) assessment for purposes of the Principles should not be affected by competitive pressure on the assessment body.
- (4) A reference in these Principles to the revocation of accreditation by an independent body or to revocation of State accreditation includes, without limitation:
 - (a) action taken by the independent body;
 - (b) action taken in a State accreditation process;
 - (c) the operation of rules of the independent body;
 - (d) the operation of rules in the State accreditation processthat has the effect of revoking, cancelling, suspending or rendering inoperative the accreditation, or an aspect of the accreditation, no matter what term is used to describe that action.

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- (5) In these Principles a reference to an application for approval under section 23DN of the Act includes without limitation an application for a variation of an approval:
- (a) by adding a kind of service not covered by the approval; or
 - (b) by changing the category covered by the approval; or
 - (c) by extending the period of the approval.

Note 1 Other words and expressions used in this instrument are defined in the Act, including *accredited pathology laboratory*, *pathology service*, *pathology services table* and *approved pathology practitioner* (see section 3 of the Act) and *pathologist*, *scientist* and *senior scientist* (see section 23DNA of the Act).

Part 2

General

6 Purpose and objects of Principles

- (1) These are the Principles to be applied by the Minister in exercising his or her powers under section 23DN of the Act:
 - (a) to approve in principle premises as an accredited pathology laboratory; and
 - (b) to refuse to approve premises as an accredited pathology laboratory; and
 - (c) to vary or revoke an approval in relation to premises.
- (2) The objects of these Principles are to:
 - (a) support the diagnosis and treatment of illness in the community by providing medicare benefits in relation to pathology services which provide reliable results; and
 - (b) reduce the risk of misdiagnosis through misleading results being provided by pathology services which do not provide reliable results; and
 - (c) maintain public confidence in pathology services which provide reliable results; and
 - (d) protect limited public funds available for medicare benefits by only providing medicare benefits in relation to pathology services which are reliable; and
 - (e) ensure that, as far as practicable, premises will be approved in principle, and will remain approved under section 23DN of the Act, for the kind of pathology services and for the category, only if it is established with a high level of confidence that the pathology services to be provided, or provided, at the premises meet, and can be expected to continue to meet, relevant standards for those kinds of services and for that category.

7 Weight to be given to views of independent body

- (1) When considering the making of a decision under section 23DN of the Act in relation to premises, the Minister must take into account:
 - (a) the most recent advisory report, if any, in relation to the premises; and
 - (b) the most recent assessment report, if any, in relation to the premises; and
 - (c) the most recent accreditation action, if any, in relation to the premises.
- (2) The Minister may take into account an advisory report, an assessment report or an accreditation action which is not the most recent.
- (3) Where there is a difference between:
 - (a) views expressed or implied by an independent body in its advisory report or assessment report, or by its accreditation action; and

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- (b) any other person's view obtained and put forward by an applicant for approval or by the holder of an approval under section 23DN of the Act,

the Minister should generally give greater weight to the views of the independent body.

8 Action may be taken despite appeal or challenge

- (1) The Minister must continue to apply the Principles, including taking into account a relevant advisory report, assessment report or accreditation action, even if a person affected by the report or accreditation action is seeking review by the independent body concerned, or by a judicial or other review body, of the report or accreditation action.
- (2) Where:
 - (a) the Minister has made a decision under section 23DN of the Act after taking into account an advisory report, assessment report or accreditation action of an independent body; and
 - (b) the independent body later varies the report or accreditation action, or a judicial or other body has set aside or varied the report or accreditation action,the Minister may, but is not obliged to, review the decision under section 23DN of the Act.
- (3) If the circumstances referred to in subsection (2) occur and the Minister does not review the decision under section 23DN of the Act, the Minister must take into account the conclusion of the independent body on review of its original report or accreditation action or, as the case may be, any order or decision of a judicial body or other body which reviewed the original report or accreditation action, when considering a new application for approval under section 23DN of the Act.

9 Assessment report by independent body

- (1) An assessment report in relation to premises must:
 - (a) be in writing; and
 - (b) be dated; and
 - (c) identify the premises subject to the report; and
 - (d) identify the independent body or special adviser providing the report; and
 - (e) be certified by an officer of the independent body to contain a true report of the views of the individuals who participated in the assessment.
- (2) An assessment report:
 - (a) must state whether or not it has been established with a high level of confidence that the pathology services provided at the premises subject to the report meet, and can be expected to continue to meet relevant standards; and

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- (b) if so established, must also state:
 - (i) by reference to items in the pathology services table, or by reference to groups of items in the pathology services table, the kind of pathology services in respect of which the premises should be approved or should remain approved; and
 - (ii) the category to which the premises should be allocated or remain allocated; and
 - (iii) the period of time for which the premises can be expected to meet relevant standards.
 - (3) Without limiting the generality of subsection (2), an assessment report must state whether or not the premises satisfy the relevant standards.
 - (4) Ordinarily, the relevant standards will consist solely of the standards in these Principles and in the accreditation materials. If it is the opinion of the independent body preparing an assessment report that other standards are also relevant to the assessment of the reliability of the services provided at the premises, then the assessment report must also include a statement identifying those other standards.

10 Other matters taken into account in making decisions

- (1) When making a decision under section 23DN of the Act in relation to premises, without limiting other sections in these Principles, the Minister may also take into account:
 - (a) any other report, assessment or decision about accreditation which has been prepared or made at any time by an independent body or in the course of State accreditation which:
 - (i) relates to the provision of pathology services at the premises; or
 - (ii) relates to any persons employed or to be employed in or otherwise associated with or to be associated with the provision of pathology services at the premises;and
 - (b) any circumstance that gives the Minister reasonable cause to believe that an approved pathology authority or an approved pathology practitioner who is, or may be, associated with the operation of the laboratory at the premises has breached an undertaking at any time; and
 - (c) if applicable, the matters set out in section 13.
- (2) Paragraphs (1) (a) and (1) (b) apply whether or not the current applicant for approval or holder of approval was associated with the premises at the time of the report, assessment or decision or at the time of the events taken into account in the report, assessment or decision or at the time the circumstance arose.

Part 3 Approval of premises

11 Approval of premises

- (1) In the absence of exceptional circumstances, the Minister must not approve in principle premises unless the Minister is satisfied with a high level of confidence that:
 - (a) the pathology services to be provided at the premises will meet relevant standards for:
 - (i) the kinds of services to be provided; and
 - (ii) for the categoryand
 - (b) without limiting paragraph (1) (a), the premises comply with the relevant requirements of:
 - (i) the Act; and
 - (ii) these Principles; and
 - (iii) the accreditation materials.
- (2) Subject to section 12, the Minister must only consider an application for approval of premises under section 23DN of the Act if the Minister is provided with an assessment report which is the most recent assessment report in relation to the premises.
- (3) In the absence of exceptional circumstances, the Minister must not approve in principle premises if within the 6 months preceding the application the last accreditation action in relation to the premises subject to the application was:
 - (a) a refusal by an independent body to grant an accreditation for pathology services provided at the premises in relation to the kinds of services or to the category subject to the application before the Minister; or
 - (b) a revocation by an independent body of an accreditation held for pathology services provided at premises in relation to the kinds of services or to the category subject to the application before the Minister.
- (4) In the absence of exceptional circumstances, the Minister must not give an approval in principle unless the Minister is satisfied that the assessment report referred to in subsection (2) supports the approval of the premises as an accredited pathology laboratory for:
 - (a) the kind of services; and
 - (b) for the category;covered by the application.
- (5) Where premises are not approved in principle on account of the operation of subsection (4), and the applicant amends the application in relation to:
 - (a) the kind of services; or

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- (b) the category;
covered by the application, the Minister may consider and deal with the amended application in accordance with these Principles as if it were an original application.

12 Approval in absence of assessment report

- (1) Where no independent body has provided an assessment report in relation to premises, the Minister may consider an application for approval under section 23DN of the Act in relation to those premises and otherwise deal with the application taking into account these Principles if:
- (a) subsection (2) applies; and
 - (b) an advisory report is provided with the application.
- (2) This section applies if an application for approval in relation to premises under section 23DN of the Act is made in relation to:
- (a) a kind of service; or
 - (b) a category;
not subject to an approval in principle or an approval under section 23DN of the Act held by the applicant for those premises at the time of making the application.
- (3) In the absence of exceptional circumstances, the Minister must approve in principle an application which relies on this section if the application is supported by a report from an independent body which states:
- (a) a representative of the independent body has visited the premises; and
 - (b) the independent body confirms that there is an appropriately equipped pathology laboratory at the premises; and
 - (c) the independent body is satisfied with a high level of confidence taking into account the arrangements in relation to the operation of the premises, that:
 - (i) the premises can be expected to meet relevant standards for a 6 month period; and
 - (ii) the premises are, or will be appropriately staffed with persons to carry out, and the persons to direct, control and supervise, the pathology services to be performed at the premises; and
 - (iii) the laboratory is, or will be at the relevant time, participating in a quality assurance program of an independent quality assurance body designed to ensure that the laboratory operates in accordance with the accreditation materials applicable to the kinds of pathology services to which approval of the premises would relate;
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- (d) the kind of pathology services in respect of which the premises should be approved (identified by reference to items in the pathology services table or by reference to groups of items in the pathology services table); and

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- (e) the category to which the premises should be allocated.

Note The independent quality assurance body mentioned in subparagraph (3) (c) (iii) might not be an independent body within the meaning of subsection 5 (1).

13 Approval where there is a State accreditation system

- (1) This section applies if the State in which the premises are located has an accreditation system under which pathology laboratories may obtain accreditation for the performance of pathology services of the kind to which the application relates.
- (2) When making a decision under section 23DN of the Act, the Minister must consider, in relation to the premises, the following matters:
 - (a) whether the premises have State accreditation; and
 - (b) if the premises have State accreditation, the services for which the accreditation is granted, the basis on which the accreditation was conferred and the period for which the accreditation operates; and
 - (c) for premises that are not so accredited, whether that circumstance is because:
 - (i) accreditation of the premises has been revoked; or
 - (ii) accreditation of the premises has been refused; or
 - (iii) accreditation of the premises has not been sought; or
 - (iv) accreditation of the premises has not been renewed;and
- (d) for premises to which paragraph (2) (c) applies, the reasons for the circumstance.

14 Period of approval

- (1) In the absence of exceptional circumstances, the Minister must not determine a period of approval which exceeds:
 - (a) the period of time for which the laboratory can be expected to meet relevant standards stated in the most recent assessment report; or
 - (b) the period of accreditation under the most recent accreditation action.
- (2) Subject to subsection (3), the Minister must not grant an approval in reliance on an advisory report for longer than 6 months.
- (3) In exceptional circumstances, the Minister may grant extensions to an approval granted in reliance on an advisory report provided that:
 - (a) each extension is supported by a further advisory report; and
 - (b) the cumulative period of those extensions does not exceed 6 months.

Note Under paragraph 23DN (2A) (c) of the Act, the period of approval for premises as an accredited pathology laboratory must not exceed 3 years.

15 Revocation of approval

- (1) In the absence of exceptional circumstances, the Minister must revoke an approval of premises if one or more of the following circumstances applies:

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- (a) the most recent assessment report states that it has not been established with a high level of confidence that the pathology services provided at the premises covered by the approval, meet, and can be expected to continue for the remainder of the period of the approval to meet, relevant standards;
 - (b) the most recent accreditation action in relation to the premises is revocation;
 - (c) State accreditation relevant to pathology services covered by the approval has been revoked or has not been renewed and the holder of the approval has not provided the Minister with a satisfactory explanation for the revocation or non-renewal of the State accreditation;
 - (d) the Minister has formed the view that the premises no longer meet the requirements for approval under subsection 11 (1).
- (2) The Minister must act in accordance with this section within 28 days of learning of the circumstances that require that action be taken.
 - (3) This section does not limit the considerations which the Minister may take into account when considering whether to revoke an approval under section 23DN of the Act.

16 Variation of approval

- (1) In the absence of exceptional circumstances, the Minister must make an appropriate variation to an approval of premises under section 23DN of the Act if one or more of the following circumstances applies:
 - (a) the most recent assessment report states that it has not been established with a high level of confidence that the pathology services provided at the premises covered by the approval meet, and can be expected to continue for the remainder of the period of the approval to meet, relevant standards in relation to some of the kinds of services covered by the approval;
 - (b) an independent body varies an accreditation relating to the kind of pathology services which may be provided at the premises by removing a service from that accreditation;
 - (c) State accreditation relevant to some of the services covered by the approval in relation to the premises has been revoked or has not been renewed and the Minister has not been provided by the holder of the approval with a satisfactory explanation of the revocation or non-renewal of the State accreditation.
- (2) The Minister must act in accordance with this section within 28 days of learning of the circumstances that require action to be taken.
- (3) This section does not limit the considerations which the Minister may take into account when considering whether to vary an approval under section 23DN of the Act.

Part 4

Categories of premises

17 Allocation of categories

- (1) The categories of accreditation of pathology laboratories for the purposes of section 23DN of the Act and the criteria applicable to each of those categories are set out in the following table:

| Category | Criteria |
|-------------------------------------|--|
| <i>Category GX (General)</i> | premises comprising a laboratory, or a number of co-located laboratories, performing services in 1 or more groups of pathology: (a) under the direction, control and full-time supervision of a pathologist, or senior scientist, who is expert in the group, or groups, concerned; and (b) at which the number of working pathologists (whether full-time or part-time) is equivalent to more than 2 full-time pathologists; |
| <i>Category GY (General)</i> | premises comprising a laboratory, or a number of co-located laboratories, performing services in 1 or more groups of pathology: (a) under the direction, control and full-time supervision of a pathologist, or senior scientist, who is expert in the group, or groups, concerned; and (b) at which the number of working pathologists (whether full-time or part-time) is equivalent to not more than 2 full-time pathologists; |
| <i>Category B (Branch)</i> | premises comprising a laboratory performing services in 1 or more groups of pathology, being a laboratory related, by appropriate arrangement, to an accredited pathology laboratory of category GX or GY, as: (a) a branch, integral (except in its location) with the category GX or GY laboratory; or (b) a member of participating laboratories in a regional pathology service; operating under: (c) the direction and control of a pathologist, or senior scientist, who is expert in the group, or groups, concerned; and (d) the supervision of at least a scientist, who is expert in the group, or groups, concerned; |
| <i>Category M (Medical)</i> | premises comprising a laboratory performing a limited range of pathology services under the direction, control and supervision of a medical practitioner, being services only for the patients of the medical practice operated by, or that employs, the medical practitioner, where the medical practice is collocated with the laboratory; |
| <i>Category S (Specialised)</i> | premises comprising a laboratory performing a limited range of pathology tests under the supervision of a person with special qualifications or skills in the field of those tests, that are tests: (a) performed for a particular target population or are of a specialised nature; and (b) are performed in the field of those special qualifications or skills. |

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- (2) In the description of category B premises, appropriate arrangement means a written arrangement that includes provisions for the direction and control of the premises by a pathologist, or senior scientist, employed in the related category GX or GY laboratory.
 - (3) The category of accreditation allocated to premises that is specified by the Minister in an approval under section 23DN of the Act must be the category set out in the table in subsection (1) that is appropriate to the premises having regard to the criteria applicable to that category.

Note For the purpose of determining the fee payable for the an application for approval as a particular category of laboratory, the categories set out below correspond to the categories specified in section 6 of the *Health Insurance (Pathology) (Fees) Act 1991*:

- (a) category GX — paragraph 6 (3) (a);
- (b) category GY — paragraph 6 (3) (b);
- (c) category B — paragraph 6 (3) (c);
- (d) category M — paragraph 6 (3) (d);
- (e) category S — paragraph 6 (3) (d).

18 Standards of direction, control, etc, of premises required

Arrangements for categories GX and GY

- (1) For a category GX or GY pathology laboratory, a supervising pathologist or senior scientist must usually be present during normal working hours and available for telephone (or other electronic) consultation at other times.

Arrangements for category B

- (2) For a category B pathology laboratory, the pathologist or senior scientist under whose direction and control pathology services are performed must:
 - (a) be employed in the related category GX or GY laboratory; and
 - (b) have qualifications and experience relevant to the laboratory's operations; and
 - (c) attend the laboratory, in accordance with subsections (3) and (4) (or arrange for the attendance of a scientist under his or her direction and control); and
 - (d) be available for telephone (or other electronic) consultation when not personally attending the laboratory; and
 - (e) monitor a system of electronic supervision of the quality of services performed.
- (3) The attendance requirement for paragraph (2) (c) is time amounting to, in a year:
 - (a) if the electronic supervision is effected by way of online reports from the supervised laboratory to the related category GX or GY pathology laboratory — the equivalent of 10 full-time days; or
 - (b) otherwise — the equivalent of 50 full-time days.

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- (4) However, attendance at supervised training, or professional development, that is conducted in the related category GX or GY laboratory and is relevant to the supervision of the laboratory is taken to satisfy the laboratory attendance requirement:
- (a) if paragraph (3) (a) applies — to the extent of the time so spent, up to the equivalent of 5 full-time days; and
 - (b) if paragraph (3) (b) applies — to the extent of the time so spent, up to the equivalent of 20 full-time days.
- (5) In addition:
- (a) externally administered quality assurance programs must be monitored by a pathologist or senior scientist employed at the related category GX or GY pathology laboratory who must endorse, in writing, the reports generated by the programs; and
 - (b) an internal quality assurance system integrated between the laboratory and the related category GX or GY laboratory must be in place.

Arrangements for category M

- (6) For a category M pathology laboratory, the supervising medical practitioner must:
- (a) usually be present when a pathology service is performed; and
 - (b) be available for telephone (or other electronic) consultation when not present; and
 - (c) have a working knowledge of the procedures for the pathology services performed and an involvement in the resolution of any problem encountered in performing those services; and
 - (d) ensure that the only services performed are services appropriate for a category M laboratory.

Arrangements for category S

- (7) For a category S pathology laboratory, the supervisor must:
- (a) usually be present when a pathology test is performed, unless, because of the training and experience of medical, scientific or technical support staff present, he or she need not be present; and
 - (b) be available for telephone (or other electronic) consultation when not present; and
 - (c) ensure that the only tests performed are tests appropriate for a category S laboratory.

Schedule 1 Accreditation materials as in force on 1 January 2003

(section 5)

Part 1 NPAAC materials

| Item | Material | Publication date |
|-------------|---|-------------------------|
| 1 | Criteria for Assessment of External Quality Assurance Programs: Vol 1 – Clinical Biochemistry, Haematology and Microbiology | 1995 |
| 2 | Criteria for Assessment of External Quality Assurance Programs: Vol 2 – Anatomical Pathology, Cytology and Transfusion Serology | 1996 |
| 3 | Requirements for Gynaecological (Cervical) Cytology | 1997 |
| 4 | Guidelines for Data Communication | 1998 |
| 5 | Information on transport of Pathology Specimens | 1998 |
| 6 | Guidelines for Laboratory Procedures Related to the Processing, Storage, and Infusion of Haemopoietic Stem Cells for Transplantation from Bone Marrow, Mobilised Peripheral Blood and Umbilical Cord Blood | 1999 |
| 7 | Requirements for Supervision of Pathology Laboratories | 1999 |
| 8 | Guidelines for Approved Pathology Collection Centres (APCCs) | 2000 |
| 9 | Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection Techniques | 2000 |
| 10 | Guidelines for Cytogenetics Laboratories | 2001 |
| 11 | Guidelines for Quality Systems in Medical Laboratories | 2001 |
| 12 | Guidelines for Performance of the Pathology Surgical Cutup | 2001 |
| 13 | Guidelines for the Use of Fluid Based Collection Systems and Automated and Semi-Automated Screening Devices in the Practice of Gynaecological (Cervical) Cytology | 2001 |
| 14 | Guidelines for Retention of Laboratory Records and Diagnostic Material | 2002 |
| 15 | Standards for Pathology Laboratories | 2002 |

Part 2 Other materials

ISO/IEC 17025 Application Document, Supplementary Requirements

Accreditation in the Field of Medical Testing, 2002, version 1