



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

made under subsection 23DNA(1) of the

*Health Insurance Act 1973*

## Compilation No. 14

**Compilation date:** 31 July 2024

**Includes amendments:** F2024L00934

**Registered:** 6 August 2024

Prepared by the Office of Parliamentary Counsel, Canberra

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## About this compilation

### This compilation

This is a compilation of the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017* that shows the text of the law as amended and in force on 31 July 2024 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## Part 1—Introductory

### 1 Name

This is the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017*.

### 3 Authority

This instrument is made under subsection 23DNA(1) of the Act.

### 4 Application of Principles

- (1) These Principles apply to the exercise by the Minister of a power under section 23DN of the Act on and 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 subsection 23DN(6A) of the Act.

### 5 Interpretation

- (1) Words in this instrument have, unless they are otherwise defined, the same meaning as in the Act.

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- accredited pathology laboratory;
- approved pathology authority;
- approved pathology practitioner;
- medical practitioner;
- pathology service;
- pathology services table.

- (2) 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 rendering of some or all of the pathology services at premises.

**accreditation materials** means each document mentioned in Schedule 1, published in the year mentioned for the document.

**Act** means the *Health Insurance Act 1973*.

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

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**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.

**designated person** means a person who is designated in an application for approval under section 23DN of the Act as the person responsible for a premises' compliance with relevant standards.

**group of pathology testing** means a group of items in the pathology services table.

**independent body** means:

- (a) NATA; and
- (b) any other organisation approved under subsection (3) by the Minister.

**NATA** means the National Association of Testing Authorities Australia (ACN 004 379 748).

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

**pathologist** means a medical practitioner recognised as a specialist for the purposes of the Act in relation to any of the specialties listed in Column 3, Item 113 of Schedule 4 of the *Health Insurance Regulations 1975*, or regulations made to replace those regulations.

**pathology discipline with a national workforce shortage** means any of the following pathology disciplines:

- (a) genomics (including cytogenetics and biochemical genetics);
- (b) immunology;
- (c) chemical pathology.

**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 section 18.

**scope of practice** means the discipline and areas of testing in which a person has:

- (a) been trained and successfully examined or assessed as competent by the relevant College, professional society, or credentialing body; and
- (b) met current Continuing Professional Development and recency of practice requirements.

**S(FC) laboratory** has the same meaning as in the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)*.

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

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**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.

- (3) Subject to subsection (4), the Minister may approve an organisation as an independent body in relation to a category or categories of laboratory for the purposes of these Principles.
- (4) In making a decision under subsection (3) the Minister must take into account that:
  - (a) ordinarily an organisation other than NATA should be approved only if there is a high level of confidence that the organisation is a suitable organisation to act as an independent body for the purposes of these Principles; and
  - (b) the objects of these Principles should not be negatively affected by competitive pressures on any independent body.
- (5) 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 process;that 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.
- (6) 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.

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## 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 that provide reliable results; and
  - (b) reduce the risk of misdiagnosis through misleading results being provided by pathology services that do not provide reliable results; and
  - (c) maintain public confidence in pathology services that provide reliable results; and
  - (d) protect limited public funds available for Medicare benefits by only providing Medicare benefits in relation to pathology services that provide reliable results; 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 rendered, or rendered, 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 or special adviser

- (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, or by a special adviser in its assessment report; and
  - (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;



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the Minister should generally give greater weight to the views of the independent body or the special adviser, as appropriate.

## **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 or special adviser concerned, or by a judicial or other review body, of the report or accreditation action.
- (2) If:
  - (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, or an assessment report of a special adviser; and
  - (b) the report or accreditation action is later varied, 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:
  - (a) the circumstances referred to in paragraphs (2)(a) and (b) occur; and
  - (b) the Minister does not review the decision under section 23DN of the Act;the Minister must take into account the circumstances referred to in paragraph (2)(b) when considering a new application for approval under section 23DN of the Act.

## **9 Assessment report by independent body or special adviser**

- (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 or by the special adviser 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 to be rendered or rendered at the premises subject to the report meet, and can be expected to continue to meet, the relevant standards; and
  - (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

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- 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; and
- (c) may state any other matter which the independent body or special adviser considers relevant.

## **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 a special adviser 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.

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## 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 rendered at the premises will meet relevant standards for:
    - (i) the kinds of services to be rendered; and
    - (ii) the category; and
  - (b) without limiting paragraph (a), the premises comply with the relevant requirements of:
    - (i) the Act; and
    - (ii) these Principles.
- (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 the subject of the application was:
  - (a) a refusal by an independent body to grant an accreditation for pathology services rendered 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 rendered 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) the category;covered by the application.
- (5) If 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
  - (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.

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## 12 Approval in absence of assessment report

- (1) If no independent body or special adviser 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 subsection 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) that a representative of the independent body has visited the premises; and
  - (b) that the independent body confirms that there is an appropriately equipped pathology laboratory at the premises; and
  - (c) that 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 render, and persons to direct, control and supervise, the pathology services to be rendered 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; and
  - (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
  - (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(2).

## 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
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accreditation for the rendering 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 accreditation of the premises:
    - (i) has been revoked; or
    - (ii) has been refused; or
    - (iii) has not been sought; or
    - (iv) 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: See also paragraph 23DN(2A)(c) of the Act.

#### **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:
- (a) the most recent assessment report states that it has not been established with a high level of confidence that the pathology services rendered 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

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- 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 that any of the circumstances in subsection (1) applies.
- (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 rendered 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 that may be rendered at the premises by removing a service from that accreditation;
- (c) State accreditation relevant to any 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 that any of the circumstances in subsection (1) applies.
- (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.

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## 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:

Item	Category	Criteria
1	<i>Category GX (General)</i>	<p>Either of the following:</p> <ul style="list-style-type: none"><li>(a) premises comprising a laboratory, or a number of co-located laboratories, that:<ul style="list-style-type: none"><li>(i) are under the full-time onsite direction and control of a designated person, who is a pathologist; and</li><li>(ii) render services in 1 or more groups of pathology testing either:<ul style="list-style-type: none"><li>(A) under the full-time supervision of a pathologist (whether or not the designated person) with the relevant scope of practice; or</li><li>(B) if the groups of pathology testing are in 1 or more pathology disciplines with a national workforce shortage and the laboratory, or co-located laboratories, are unable to recruit a full-time pathologist with the relevant scope of practice—under the supervision of a pathologist (whether or not the designated person);</li></ul></li></ul></li><li>(b) premises comprising a laboratory, a number of co-located laboratories or a network of laboratories, that:<ul style="list-style-type: none"><li>(i) are a recognised national blood service; and</li><li>(ii) are under the full-time direction, control and supervision of a designated person, who is a pathologist with the relevant scope of practice; and</li><li>(iii) render a limited range of pathology testing under the full-time supervision of a pathologist (whether or not the designated person) with the relevant scope of practice.</li></ul></li></ul>
2	<i>Category GY (General)</i>	<p>Premises comprising a laboratory, or a number of co-located laboratories, that:</p> <ul style="list-style-type: none"><li>(a) are related by an appropriate arrangement to a GX laboratory; and</li><li>(b) are under the direction and control of the designated person of the related GX laboratory; and</li><li>(c) render services in 1 or more groups of pathology testing either:<ul style="list-style-type: none"><li>(i) under the full-time onsite supervision of a pathologist (whether or not the designated person) with the relevant scope of practice; or</li></ul></li></ul>

Item	Category	Criteria
		<ul style="list-style-type: none"> <li>(ii) if:               <ul style="list-style-type: none"> <li>(A) the groups of pathology testing are in 1 or more pathology disciplines with a national workforce shortage; and</li> <li>(B) the laboratory, or co-located laboratories, are unable to recruit a full-time pathologist with the relevant scope of practice;                   <ul style="list-style-type: none"> <li>under the supervision of a pathologist (whether or not the designated person);</li> <li>whether or not the premises also renders services in 1 or more groups of pathology testing under the supervision of a pathologist with the relevant scope of practice who is situated in:</li> </ul> </li> <li>(d) the related GX laboratory (whether or not the pathologist is the designated person); or</li> <li>(e) another GY laboratory that is related to that GX laboratory.</li> </ul> </li> </ul>
3	<i>Category B (Branch)</i>	<p>Premises comprising a laboratory, or a number of co-located laboratories, that:</p> <ul style="list-style-type: none"> <li>(a) are related by an appropriate arrangement to a GX laboratory or GY laboratory; and</li> <li>(b) are under the direction and control of the same designated person as the related laboratory; and</li> <li>(c) render services in 1 or more groups of pathology testing under the supervision of a pathologist (whether or not the designated person) from a laboratory within the pathology network.</li> </ul>
4	<i>Category M (Medical)</i>	<p>Premises comprising a laboratory that:</p> <ul style="list-style-type: none"> <li>(a) is under the full-time onsite direction, control and supervision of a designated person, who is a medical practitioner; and</li> <li>(b) renders a limited range of pathology testing only for the patients of a medical practice that:           <ul style="list-style-type: none"> <li>(i) is operated by, or employs, the designated person; and</li> <li>(ii) is co-located with the laboratory.</li> </ul> </li> </ul>
5	<i>Category S (Specialised)</i>	<p>Any of the following:</p> <ul style="list-style-type: none"> <li>(a) premises comprising a laboratory that:           <ul style="list-style-type: none"> <li>(i) is under the full-time direction, control and supervision of a designated person, who is:               <ul style="list-style-type: none"> <li>(A) a medical practitioner with specialised scope of practice; and</li> <li>(B) not a pathologist; and</li> </ul> </li> <li>(ii) renders a limited range of pathology testing:               <ul style="list-style-type: none"> <li>(A) for a target patient population or of a specialised nature; and</li> <li>(B) that is restricted to the field of pathology testing directly related to the scope of practice of the designated person;</li> </ul> </li> </ul> </li> <li>(b) premises comprising a laboratory that:           <ul style="list-style-type: none"> <li>(i) operates as a branch of a laboratory which meets the criteria in paragraph (a); and</li> </ul> </li> </ul>



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Item	Category	Criteria
		(ii) is under the direction, control and supervision of the designated person of that laboratory;
		(c) premises comprising a laboratory that:
		(i) is under the full-time direction, control and supervision of a designated person, who is:
		(A) a medical practitioner; and
		(B) not a pathologist; and
		(ii) renders a limited range of pathology testing:
		(A) for a target patient population or of a specialised nature; and
		(B) that is in 1 or more pathology disciplines with a national workforce shortage;
		(d) premises comprising an S(FC) laboratory that:
		(i) is under the full-time direction, control and supervision of a designated person, who is:
		(A) a medical practitioner with a specialised scope of practice; and
		(B) not a pathologist; and
		(ii) renders a limited range of pathology testing that is:
		(A) restricted to tests related to fertility control testing; and
		(B) under the full-time supervision of the designated person.

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(2) In the table in subsection (1), **appropriate arrangement** means a written arrangement that includes provision for the direction, control and supervision of the relevant 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 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 and supervision of premises required

- (1) Premises must be under the direction, control and supervision of a designated person, who:
- (a) possesses appropriate qualification; and
  - (b) is competent; and
  - (c) has relevant scope of practice;
- to fulfil their obligations under this section.
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- (2) The designated person is responsible for premises' compliance with relevant standards.
  - (3) Without limiting subsection (2), the designated person is responsible for compliance with the standards of direction, control and supervision that apply to the relevant category of laboratory under the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)*, including in relation to:
    - (a) the clinical governance of the laboratory; and
    - (b) oversight and management of the laboratory's staff and processes to ensure ethical patient care and the provision of accurate and timely test results.
  - (4) The designated person may only supervise pathology testing within his or her scope of practice.
  - (5) The responsibilities of the designated person for premises under this section may be delegated, but only in accordance with the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)*.

Note: The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)* is listed in Schedule 1.

- (6) Paragraph (1)(c) and subsection (4) do not apply to a designated person of a premises that:
  - (a) comprises a category S laboratory; and
  - (b) renders services in 1 or more groups of pathology testing that are in 1 or more pathology disciplines with a national workforce shortage.

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## Schedule 1—Accreditation materials

Note: See definition of accreditation materials in subsection 5(2).

### 1 NPAAC materials

The following table has effect for the purposes of the definition of *accreditation materials* in subsection 5(2).

Item	Material	Publication year
1	Requirements for the Estimation of Measurement Uncertainty	2007
2	Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection) (Third Edition 2013)	2013
3	Requirements for Medical Testing for Human Genetic Variation (Third Edition 2022)	2022
4	Requirements for Information Communication and Reporting (Fifth Edition 2022)	2022
5	Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (Fourth Edition 2023)	2023
7	Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013)	2013
8	Requirements for the Facilities and Operation of Mortuaries (Third Edition 2013)	2013
9	Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fifth Edition 2022)	2022
10	Requirements for the Performance of Anatomical Pathology Cut-Up (Fourth Edition 2013)	2013
11	Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015)	2015
12	Requirements Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)	2021
13	Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies (First Edition 2017)	2017
14	Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019)	2019

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<b>Item</b>	<b>Material</b>	<b>Publication year</b>
15	Requirements for Semen Analysis (First Edition 2017)	2017
16	Requirements for Transfusion Laboratory Practice (Fifth Edition 2022)	2022
17	Requirements for Medical Pathology Services (Third Edition 2018)	2018
18	Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2017)	2018
19	Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Seventh Edition 2023)	2023
20	Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Fourth Edition 2018)	2018
21	Requirements for the Retention of Laboratory Records and Diagnostic Material (Ninth Edition 2022)	2022
22	Requirements for Validation of Self-Collected Vaginal Swabs for use in the National Cervical Screening Program (First Edition 2019)	2019
23	Requirements for the Communication of High Risk Pathology Results (First Edition 2020)	2020
23A	Requirements for Point of Care Testing (Second Edition 2021)	2021
24	Requirements for the Use of Digital Images as an Alternative to Direct Microscopy (First Edition 2021)	2021

Note: The documents mentioned in Schedule 1 could in 2024 be viewed on the Australian Commission on Safety and Quality in Health Care's pathology accreditation standards webpage.

## **2 Application of the *Requirements for Medical Pathology Services (Third Edition 2018)***

### *Scope*

- (1) This clause applies in relation to a designated person of a premises that:
- (a) comprises a category S laboratory; and
  - (b) renders services in 1 or more groups of pathology testing that are in 1 or more pathology disciplines with a national workforce shortage.

### *Application*

- (2) For the purposes of this instrument, the *Requirements for Medical Pathology Services (Third Edition 2018)* (mentioned in table item 17 of clause 1 of this Schedule) apply, in relation to the designated person, as if the definition of **designated person** in those requirements did not include a reference to relevant scope of practice.

## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

## Endnotes

### Endnote 2—Abbreviation key

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#### Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

## Endnote 3—Legislation history

**Endnote 3—Legislation history**

<b>Name</b>	<b>Registration</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017	28 Sept 2017 (F2017L01291)	29 Sept 2017 (s 2)	
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 1) 2018	28 June 2018 (F2018L00933)	Sch 2: 1 Dec 2018 (s 2(1) item 3) Remainder: 29 June 2018 (s 2(1) items 1, 2)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 2) 2018	29 Nov 2018 (F2018L01633)	Sch 1: 1 Dec 2018 (s 2(1) item 2) Sch 2: 1 Aug 2019 (s 2(1) item 3)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 1) 2019	31 July 2019 (F2019L01030)	Sch 1: 1 Aug 2019 (s 2(1) item 2)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment Instrument (No. 2) 2019	26 Sept 2019 (F2019L01278)	Sch 1: 27 Sept 2019 (s 2(1) item 2)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Transitional Arrangements) Principles 2020	24 Dec 2020 (F2020L01718)	1 Jan 2021 (s 2(1) item 1)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles 2021	30 July 2021 (F2021L01053)	Sch 1 (items 1–16): 1 Aug 2021 (s 2(1) item 2) Sch 1 (item 17): 1 Jan 2022 (s 2(1) item 3) Sch 1 (item 18): 1 Aug 2022 (s 2(1) item 4)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2021	20 Dec 2021 (F2021L01850)	Sch 1 (items 1, 2): 1 Jan 2022 (s 2(1) item 2) Sch 1 (item 3): 1 Feb 2022 (s 2(1) item 3)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2022	21 Apr 2022 (F2022L00621)	22 Apr 2022 (s 2(1))	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2023	23 Feb 2023 (F2023L00134)	1 Mar 2023 (s 2(1) item 1)	—

## Endnotes

### Endnote 3—Legislation history

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<b>Name</b>	<b>Registration</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2023	20 Apr 2023 (F2023L00454)	1 May 2023 (s 2(1) item 1)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.3) 2023	26 July 2023 (F2023L01032)	1 Aug 2023 (s 2(1) item 1)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.1) 2024	30 Jan 2024 (F2024L00107)	Repealed before commencing (s 2(1) item 1)	—
<b>as repealed by</b>			
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2024	30 July 2024 (F2024L00934)	Sch 2: 31 July 2024 (s 2(1) item 1)	—
Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles (No.2) 2024	30 July 2024 (F2024L00934)	Sch 1: 31 July 2024 (s 2(1) item 1)	—



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**Endnote 4—Amendment history**

<b>Provision affected</b>	<b>How affected</b>
<b>Part 1</b>	
s 2.....	rep LA s 48D
s 4.....	(2) rep LA s 48C
s 5.....	am F2018L00933; F2018L01633; F2021L01053; F2023L01032
<b>Part 2</b>	
s 7.....	am F2018L00933
s 8.....	am F2018L00933
s 9.....	am F2018L00933
s 10.....	am F2018L00933
<b>Part 3</b>	
s 11.....	am F2018L00933
s 12.....	am F2018L00933
<b>Part 4</b>	
s 17.....	am F2018L00933; F2018L01633; F2020L01718; F2021L01053
s 18.....	rs F2018L00933; F2018L01633 am F2021L01053; F2023L01032
Part 5.....	ad F2019L01030 rep 1 Aug 2021 (s 21)
s 19.....	ad F2019L01030 am F2020L01718 rep 1 Aug 2021 (s 21)
s 20.....	ad F2020L01718 rep 1 Aug 2021 (s 21)
s 21.....	ad F2020L01718 rep 1 Aug 2021 (s 21)
<b>Schedule 1</b>	
Schedule 1.....	rs F2018L00933 am F2018L01633; F2019L01278; F2021L01053; F2021L01850 ed C7 am F2022L00621 ed C9 am F2023L00134 ed C11 am F2023L00454; F2023L01032; F2024L00934
Schedule 2.....	am F2018L00933 rep F2018L00933

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