

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

**REQUIREMENTS FOR THE
SUPERVISION OF PATHOLOGY
LABORATORIES**

(2007 Edition)

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Australian Government Department of Health and Ageing

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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards, and initiate and promote guidelines and education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Introduction

This document, *Requirements for the Supervision of Pathology Laboratories*, details the National Pathology Accreditation Advisory Council (NPAAC) standards used to assure the safety, quality and efficacy of pathology testing through effective supervision.

For the application of the *Health Insurance (Accredited Pathology Laboratory - Approval) Principles 1999* (or equivalent), laboratories have been categorised into groups to facilitate the definition of appropriate levels of supervision for particular types of laboratories.

The principles for the approval of premises as an accredited pathology laboratory were first determined in 1987. There were eight categories to which laboratories could be assigned for accreditation purposes, depending on the location of the premises and who is responsible for day-to-day supervision. These categories and definitions were reviewed in 1993 and it was agreed that, for the purposes of accreditation, laboratories be divided into five categories, defined by who is responsible for the day-to-day supervision.

In 2004, NPAAC again reviewed the changes that have taken place within pathology laboratories, in laboratory technology, information technology, electronic supervision and current laboratory work practices.

In each section of this document, points deemed important for practice are identified as either 'standards' or 'guidelines'.

- A standard is the minimum requirement for a procedure, method, staffing resource or laboratory facility that is required before a laboratory can attain accreditation — standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2**). The use of the verbs 'shall' and 'must' in each standard within this document indicates a mandatory requirement for pathology practice.
- A guideline is a consensus recommendation for best practice and should be used if a higher standard of practice is appropriate, particularly when setting up or modifying a laboratory test, or when contamination problems have occurred — guidelines are prefaced with a 'G' (e.g. G2.2) and are numbered to correspond with their associated standard. 'Should' is used to indicate guidelines or recommendations where compliance would be expected for good laboratory practice.
- A commentary is provided to give clarification to the standards and guidelines as well as to provide examples and guidance on interpretation. Commentaries are placed where they add the most value, and may be **normative** or **informative** depending on both the content and the context of whether they are associated with a Standard or a Guideline. Note that when Comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached.

While this document is for use in the accreditation process, comment from users would be appreciated and can be directed to:

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Definitions

The following definitions are based on the *Health Insurance Act 1973*, but have been amended for the purposes of this document.

Medical Practitioner[†] means a person registered or licensed as a medical practitioner under a law of a State or Territory that provides for the registration or licensing of medical practitioners but does not include a person so registered or licensed:

- (a) whose registration, or license to practise, as a medical practitioner in any State or Territory has been suspended, or cancelled, following an inquiry relating to his or her conduct; and
- (b) who has not, after that suspension or cancellation, again been authorised to register or practise as a medical practitioner in that State or Territory.

Pathologist means medical practitioner who has been recognised for the purposes of the Health Insurance Act 1973 as a specialist in one of the pathology specialties listed in Item 113 of Schedule 4 of the Health Insurance Regulations 1975.

Supervising Pathologist means a Pathologist who has had training to allow him/her to supervise a medical testing laboratory.

Scientist means a person who possesses one of the following qualifications:

- (a) a degree in science or applied science with subjects relevant to the field of pathology awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a professional class of membership of the Australasian Association of Clinical Biochemists, Australian Institute of Medical Scientists, Australian Society for Microbiology, Australian Society of Cytology, Human Genetics Society of Australasia
- (b) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973
- (c) a qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the *Health Insurance Act 1973*, to be equivalent to a qualification referred to in paragraph (a) or (b) of this definition.

Senior scientist[‡] means a scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications:

- (a) a Doctorate of Philosophy in a subject relevant to the field of pathology

[†] This definition is in accordance with the *Health Insurance Act 1973*.

[‡] This definition applies specifically to this document and does not relate to classification, employment or conditions within State or Territory Awards.

- (b) a Fellowship of the Australasian Association of Clinical Biochemists
- (c) a Fellowship of the Australian Institute of Medical Scientists
- (d) a Fellowship of the Australian Society for Microbiology (medical/clinical microbiology)
- (e) a Fellowship of the Human Genetics Society of Australasia
- (f) a qualification that the Minister determines, pursuant to the definition of ‘scientist’ in subsection 23DNA(4) of the *Health Insurance Act 1973*, to be equivalent to a qualification referred to in paragraph (a), (b), (c), (d) or (e) of this definition.

Laboratory means premises which, in addition to fulfilling the requirements of the Act, may include a facility or facilities remote from the laboratory site providing it is conducting an approved range of Point of Care Testing under the direct supervision of the designated accredited laboratory.

Point of Care Testing means testing performed outside a central laboratory environment, generally nearer to, or at the site of, the patient.

Laboratory categories

Introduction

There are five laboratory categories, as specified in Section 17 of the *Health Insurance (Accredited Pathology Laboratory – Approval) Principles 2002*:

- Category GX (General)
- Category GY (General)
- Category B (Branch)
- Category M (Medical Practice)
- Category S (Specialised).

The different categories are described in detail below. Standard 1 of this document outlines the staffing and supervision requirements for each of the five categories; Standard 2 outlines the consultation requirements. The range of tests performed in each category of laboratory must be approved by the accrediting agency.

Categories GX and GY (General)

These categories are used for both large and small multidiscipline or general laboratories providing comprehensive services. They are also used for limited or single discipline laboratories.

A Category GX laboratory comprises of 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 supervising 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.

A Category GY laboratory comprises of 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 supervising 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.

Where a laboratory is operating for less than a full-time equivalent working week then the requirements for supervision in these categories must apply for the hours of operation of that laboratory.

Category B (Branch)

This category is used for a laboratory that is either:

- a) an integral part of a Category GX or GY laboratory, apart from its geographic location

or

- b) a part of a regional pathology service.

A Category B laboratory shall have a documented agreement with a Category GX or GY laboratory to ensure that the range of pathology tests provided and the standard of work in the laboratory is under the direction and control of a designated supervising pathologist or senior scientist of an accredited Category GX or GY laboratory.

Category M (Medical practice)

This category is used for a laboratory based in a medical practice, which is under the supervision of a registered medical practitioner of that medical practice. It provides a limited range of approved tests, only for the patients of the medical practice at which the laboratory is situated. A laboratory in this category shall not provide tests on patients referred from other medical practices or from medical practitioners other than those of the medical practice at which the laboratory is sited.

Category S (Specialised)

This category is used for either:

- a) a laboratory in which a limited range of tests is performed on a particular patient population

or

- b) a laboratory in which a limited range of tests (services) is performed, that are of a specialised nature and are performed under the supervision of a person having special qualifications or skills in the field of those services.

Where the supervisor is a medical practitioner, approved pathology services may be provided for patients of the supervising practitioner and for those referred by other practitioners.

Standard 1 — Staffing and supervision

S1.1 There shall be sufficient professional and support staff with adequate training and experience to supervise and conduct the work of the laboratory.

S1.2 The designated person in charge, under whose direction and control the accredited pathology laboratory operates must:

- a) **determine the range of tests provided, their methods and procedures**
- b) **approve and be responsible for operational practices and staffing of the laboratory (including staff training)**
- c) **ensure regular review of the laboratory's quality systems, proficiency testing data, laboratory reports and discussion of all aspects of the laboratory's performance with the scientific staff**
- d) **ensure appropriate consultation on medical and scientific issues (see Standard 2 for further information)**
- e) **ensure that the procedures used and the tests performed are within the scope of the education, training, continuing professional development and experience of the individual staff, and be able to demonstrate (by appropriate documentation) that this is the case**
- f) **ensure that there is continuity of overall supervision in situations where the supervision is provided by more than one person**
- g) **ensure that work performed at the laboratory outside normal working hours is carried out only by scientific or technical staff with appropriate training and experience, approved by the supervising pathologist or senior scientist.**

S1.3 In a Category GX or GY laboratory the supervising pathologist(s) or senior scientist(s) must be present during normal working hours of the laboratory. Where a Category GX or GY laboratory is supervised by a senior scientist there must also be a pathologist present during normal working hours of the laboratory.

Commentary on staffing and supervision

C1.1 The following commentary discusses staffing and supervision for each of the five laboratory categories. Further information on consultation can be found in Standard 2.

Categories GX and GY

C1.2 The supervising pathologist(s) or senior scientist(s) must be present during normal working hours of the laboratory. For the purposes of this document, "must be present" includes being contactable for consultation but not being in physical attendance at the Category GX/GY laboratory:

- (a) to provide supervisory visits to related Category B laboratories within the same organisation as the Category GX/GY laboratory

- (b) for bona fide absences for professional purposes or due to illness or personal necessity for up to seven consecutive work days.

Category B

C1.3 The designated supervising pathologist or senior scientist from the Category GX or GY laboratory, under whose direction and control the Category B laboratory operates, shall:

- a) be responsible for ensuring control over the monitoring and rendering of services, including oversight of supervision
- b) be responsible for ensuring that the laboratory computer system fulfils its function in monitoring and rendering of services.
- c) review and countersign proficiency testing results
- d) be available for telephone consultation or equivalent when not personally in attendance at the laboratory.

C1.4 Onsite staff at a Category B laboratory shall include a supervising scientist with appropriate qualifications and a minimum of 2 years supervised experience relevant to the laboratory's operation. The onsite supervising scientist* must be present at the laboratory during normal working hours.

C1.5 The Category B laboratory shall be an integral part of, or maintain operational systems that are consistent with, the quality system of the Category GX or GY laboratory.

C1.6 Where the Category B laboratory computer system is an integral part of, or sufficiently compatible with, the Category GX or GY laboratory computer system to allow control over the monitoring and rendering of services, the following conditions apply for the purposes of electronic supervision:

- a) supervising pathologists, pathologists or scientists from the Category GX or GY laboratory must spend at least 10 full-time-equivalent (FTE) days per year at the branch laboratory
- b) at least one day of these FTE visits must be from a supervising pathologist or pathologist
- c) time that scientists or technicians from the Category B laboratory spend in supervised training or professional development in the Category GX or GY laboratory (or at an appropriate training location) may be offset against the aforementioned supervisory requirements, up to a maximum of 5 days per year
- d) where there is documented teleconferencing and videoconferencing management of the Category B laboratory, time spent in such activities may be offset against the aforementioned supervisory requirements, up to a maximum of 2 days per year

* Where more than one scientist provides the supervision, a designated scientist must ensure the continuity of overall onsite scientific supervision

C1.7 Where the Category B laboratory computer system is **not** an integral part of, or is **not** sufficiently compatible with, the Category GX or GY laboratory computer system to allow control over the monitoring and rendering of services, the following conditions apply for the purposes of electronic supervision:

- a) supervising pathologists, pathologists or scientists from the Category GX or GY laboratory must spend no less than 50 FTE days per year at the branch laboratory
- b) time that scientists from the Category B laboratory spend in supervised training or professional development in the Category GX or GY laboratory (or at an appropriate training location) may be offset against the aforementioned supervisory requirements, up to a maximum of 20 days per year.

C1.8 Whilst recruiting a supervising scientist, in the event of exceptional circumstances, a person who is a scientific officer of more than 1 but less than 2 years experience or a technical officer with at least 10 years experience relevant to the work of the specified laboratory, may be deemed to supervise a category B laboratory, provided:

- a) the supervising pathologists, pathologists or scientists from the GX or GY laboratory must spend no less than 50 FTE days per year and
- b) the officer must spend at least 10 FTE days per year in supervised training or professional development in the Category GX or GY laboratory.

Category M

C1.9 The medical practitioner shall:

- a) be responsible for the proper performance of tests
- b) have a working knowledge of each test procedure
- c) review and countersign proficiency testing results
- d) be involved in the resolution of problems encountered with the laboratory work.
- e) be responsible for the implementation of the test results.

C1.10 The medical practitioner will usually be present while the testing is being carried out.

Category S

C1.11 The supervisor of a Category S laboratory must be present at all times that tests are performed unless there are medical, scientific or technical support staff, approved by the supervisor, whose qualifications and experience are adequate for the work performed at the laboratory. Where such support staff are available, the supervisor shall maintain regular contact with the laboratory and be available for consultation at all times.

C1.12 The supervisor of a Category S laboratory shall review and countersign proficiency testing results.

Standard 2 — Consultation

S2.1 Laboratories shall have staff who can advise clinicians on the evaluation and interpretation of results of laboratory examinations.

S2.2 An essential part of laboratory activity is the provision of a consultative service to the clinician. The consulting service shall be readily available and the clinician shall be able to obtain authoritative advice from the laboratory on:

- a) the precision and accuracy of methods used in the laboratory**
- b) the significance of results in relation to the laboratory's reference values**
- c) the scientific basis of the results**
- d) the clinical significance of the requested procedure and its fitness for purpose (suitability to solve the clinical problem in question)**
- e) further procedures that may be helpful.**

Commentary on consultation

C2.1 The following commentary discusses consultation arrangements for each of the five laboratory categories. Further information on staffing and supervision can be found in Standard 1.

Category GX and GY laboratories

C2.2 For Category GX and GY laboratories, pathologists or senior scientists with appropriate qualifications must be available for consultation.

Category B laboratory

C2.3 For a Category B laboratory, a pathologist or senior scientist with appropriate qualifications, must be available at either at the Category B laboratory or at the supervising Category GX or GY laboratory during normal working hours, and must be available for telephone consultation at other times.

Category M laboratory

C2.4 For a Category M laboratory, the registered medical practitioner supervising the laboratory should either be present at the medical practice, or available to the other medical practitioners of that practice, for consultation and advice on the evaluation and interpretation of results of tests performed in the laboratory, and the precision and accuracy of the methods employed.

Category S laboratory

C2.5 For a Category S laboratory, the supervisor shall ensure that consultative advice is available at all times (either from the supervisor or from another, suitably qualified, person).

Further information

Other NPAAC documents are available from:

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