

## Policy

Subject: **Supervision of Diagnostic Laboratories in Australia**  
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The Royal College of Pathologists of Australasia is committed to assisting in setting professional standards for the provision of quality laboratory medical services. An important component of this is the appropriate governance and supervision of laboratories as set out in the National Pathology Accreditation Advisory Committee (NPAAC) standard [\*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories \(Sixth Edition 2021\)\*](#).

Clinical governance is defined in that document as a “systematic and integrated approach to assurance and review of clinical responsibility and accountability that continually improves quality and safety of services provided to patients resulting in optimal patient outcomes”. The Designated Person is ultimately responsible for clinical governance, including but not limited to laboratory supervision with an emphasis on risk analysis determining provision of service.

The purpose of this Policy is to delineate the elements of the NPAAC document, particularly to assist those assessing laboratories for NATA/RCPA accreditation. Governance structure and supervision requirements are considered together in accreditation assessment.

It is the College’s position that satisfactory supervision of a laboratory occurs when medical and scientific supervisors ensure that all elements of the following three areas have been executed:

1. Pre-analytic, analytic and post-analytic aspects of laboratory testing. Supervisors are expected to be competent in these areas in their own field of testing:
  - collection, preparation and analysis of clinical specimens including the determination of the suitability of both the sample type and labelling
  - advice on the interpretation, correlation and validation of results of an investigation using knowledge of method(s), analytical principles and clinical information
  - reporting, issue and retention of Laboratory results
  - maintenance of documentation, equipment, resources, reagents and consumables
  - maintenance and promotion of safe working practices, biohazard awareness and management

- professional accountability and participation in continuing professional development for themselves, and for their staff consistent with their responsibilities
- responsibility for professional practice including scientific equipment and test selection, development and use of laboratory examinations, including the range of testing performed, their internal quality control and their external quality assurance
- evaluation, selection and monitoring of reference laboratories where such services are required
- liaison with health workers and others to continuously improve the service
- participation in education and training of health workers and others
- medical governance and ethical practice in relation to the quality of patient care
- development and operation of a risk management system and an incident reporting and investigation system.

## 2. Clinical Governance and Laboratory Management

- at least yearly performance review of the immediate reporting senior staff and discussion of issues arising from their performance review of their staff
- documented review of incidents revealed by the quality system with corrective action and further follow-up to ensure that the problem has been corrected by the action
- documented review of all external quality assurance program participation to ensure full participation, review of results and corrective actions when discordant results are obtained
- documented review of internal quality controls including audits and any corrective actions
- documented review of customer feedback including complaints and their corrective actions
- documented review of safety records, incidents and corrective actions
- discussion with staff regarding any proposed new tests or equipment
- physical inspection of the laboratory
- documented evidence of staff meetings with educational component as well as Workplace Health and Safety
- review of continuing education both internal and external, including its extent and relevance
- where the laboratory provides services to a hospital or is sited in a hospital, documentary evidence of liaison with clinical and administrative staff of the hospital

## 3. Operational Requirements

- All areas of testing in a laboratory must be able to be mapped to a medical or scientific supervisor with relevant scope of practice and competency;
- Nominated supervisors must demonstrate that they have provided sufficient time to execute their duties including review of methods and assay performance; and,
- Supervisors must demonstrate that they have implemented systems to monitor quality measures including review of QC and QA.

For category B laboratories, this means that a pathologist in the relevant area must monitor the tests that are performed in that laboratory within their scope of practice. For example, for a laboratory that does chemistry tests there needs to be a chemical pathologist, for microbiology tests a laboratory microbiologist, and for haematology and blood banking a laboratory haematologist involved in the supervision of these areas of the laboratory testing.

Often category B laboratories will have a resident pathologist or pathologists who are working in the area of anatomical pathology. They are competent to supervise this area of the laboratory as well as provide clinical and medical governance for the laboratory generally. They do not have the appropriate qualifications or competency to supervise other areas of testing outside the discipline of anatomical pathology.

Networks of laboratories should have a single nominated category GX laboratory with full-time onsite pathologists with appropriate scope of practice in all the areas of testing throughout the whole network. These pathologists will have a supervisory responsibility for their area of testing both in the category GX laboratory, those dependent category B and, if applicable, GY laboratories.

For category G laboratories, this means that a specialist pathologist with the relevant scope of practice must monitor the tests that are performed in that laboratory in the area of their scope of practice. For example, for a laboratory that does chemistry tests, there needs to be a chemical pathologist or general pathologist involved in the supervision of these areas of the laboratory testing, etc.

A networked category GX laboratory that does testing outside the area of competency of the resident pathologist(s) should be re-classified as a category GY or B laboratory and those areas of testing should be supervised by the appropriate pathologists from the main GX laboratory.

RCPA members involved in assessing the supervision of laboratories should also refer to [RCPA Guideline: Fellows as Assessors for NATA/RCPA Accreditation](#)