



Understanding the NPAAC Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)

The NPAAC Tier 3A document *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* has been recently published. The Requirements include a risk based approach to governance and outlines the supervision arrangements for categories of laboratories, including responsibilities of the *designated person*.

The revised Supervision Requirements will come into effect on 1 August 2019.

The intention of the Requirements is to describe optimal supervision and clinical governance arrangements in pathology laboratories that promote the safe performance of pathology services and improve patient outcomes.

The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories* describes professional accountability in a medical pathology service where a pathology referral is a medical consultation between medical specialists. The professional accountability structure is not necessarily the same as the organisational management structure.

The following addresses some of the common questions and attempts to provide additional guidance to pathology laboratories and the independent assessment body.

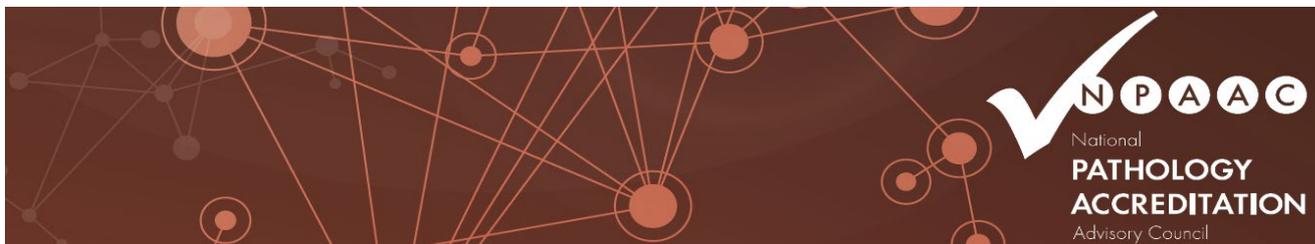
Frequently Asked Questions

Q: Does a designated person have to be full time onsite in the laboratory?

A key requirement of the designated person is that the individual is responsible *full time* for the clinical governance of the laboratory. For example, if the designated person is based in a Category GX laboratory, they have full time unequivocal responsibility for clinical governance of the laboratory. They are not required to be full time *on site* as they may be visiting other laboratories if the GX laboratory is a part of a network.

Q: Can a designated person be the one and same as a supervising Pathologist?

Yes, if they are supervising tests directly related to their qualifications, competencies and current scope of practice.



Q: Can there be more than one designated person for a pathology laboratory?

No. There can only be one designated person in a Category GX, S or M pathology laboratory. This is a registered medical practitioner who is accountable for the clinical governance of the laboratory or network of laboratories.

Q: Is it acceptable if a designated person, who is full-time does a proportion of clinical work, during operational hours?

This is acceptable if the clinical work is related to pathology activities and if there are appropriate supervision arrangements in place for pathology testing. Microbiologists, Immunologists and Haematologists may, for example, take part in ICU rounds or patient consultations.

A designated person attending clinics must be able to demonstrate to the independent accrediting body that even whilst doing so, the designated person maintains their responsibility to the laboratory and are able to perform their duties.

Q: Does supervision need to be full-time onsite by a Pathologist with the relevant scope of practice?

For a GX laboratory there must be at least one full time equivalent, in aggregate, onsite Pathologist with the relevant Scope of Practice for each pathology test offered by the laboratory.

Q: If I am a Pathologist with a relevant Scope of Practice but work part-time, can I supervise testing?

I can supervise testing in a Category GX laboratory within my scope of practice as part of shared full time equivalent, in aggregate, onsite supervision of the pathology tests offered by the laboratory within my scope of practice.

Or

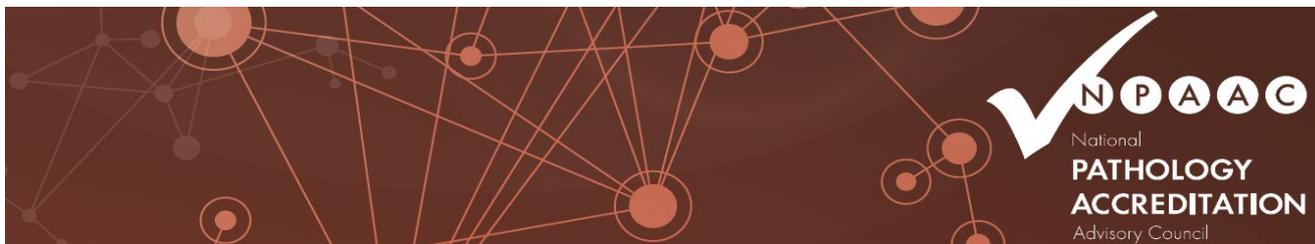
I can supervise testing in a Category GY laboratory within my scope of practice as part of shared full time equivalent, in aggregate, onsite supervision of the pathology tests offered by the laboratory within my scope of practice.

Or

I can be delegated supervision of those tests within my scope of practice offered by a Category GY laboratory where there is no full time, in aggregate, onsite pathologist supervision with relevant Scope of Practice, or those tests offered by a Category B laboratory within my scope of practice, provided that there is full time onsite pathologist supervision in the same scope of practice at the related Category GX laboratory.

and

I can also be delegated supervision responsibility for tests within my scope of practice offered by any Category GY or B laboratories in the same Pathology Network I am part of.



Q: To which laboratory category is a pathology service where the designated person is a pathologist to be assigned?

These services are to be provided in Category GX, GY and B laboratories.

Q: What is risk assessment?

The laboratory must have a Risk Management Process which is clearly identified within the laboratory policy framework. Standards related to risk management are outlined in Requirements for Medical Pathology Services S3.1-4 and Appendix A of that Standard. .

Q: Who can perform supervision visits?

Supervising Pathologist(s), Pathologists, Clinical Scientists, Quality Managers or Scientists (see S3.6, S3.7, and S3.10)

Q: Can a pathologist with a specific scope of practice supervise testing with their scope of practice if they are situated at a GX laboratory and testing is performed at a distant Category G or B laboratory?

No. Any risk based assessment of supervision arrangements would dictate that the supervising pathologist be at the site where testing is conducted, in this example, at the other G or B laboratory.

Q: Can a medical specialist practitioner with a specific scope of practice supervise testing with their scope of practice if they are situated at a Category S laboratory and all testing is performed at a Category SB laboratory?

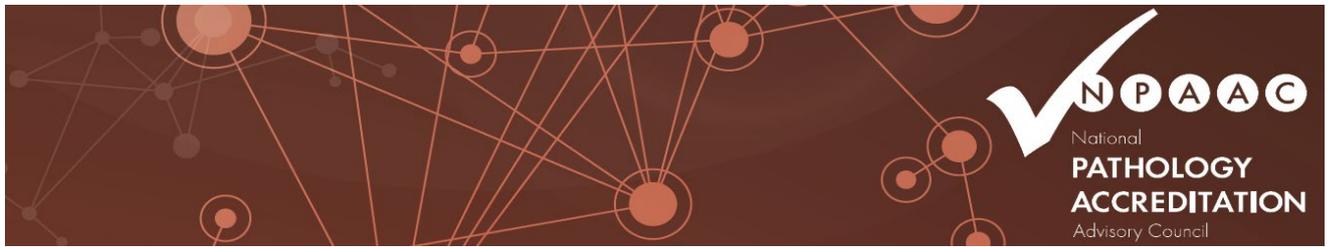
No. A risk based assessment of supervision arrangements requires that the supervising medical specialist has a direct in person role for testing. Testing can only be offered at the SB laboratory if that testing is offered at the S laboratory and supervised by a medical specialist with scope of practice and competency in this area.

Q: In terms of leave cover, what is acceptable? For example, can a General Pathologist with a scope of practice in a sub discipline provide supervision for another sub discipline within the GX laboratory?

The principles for adequate supervision are that the supervisor is appropriately qualified and with a relevant scope of practice and Continuing Professional Development in the area of testing.

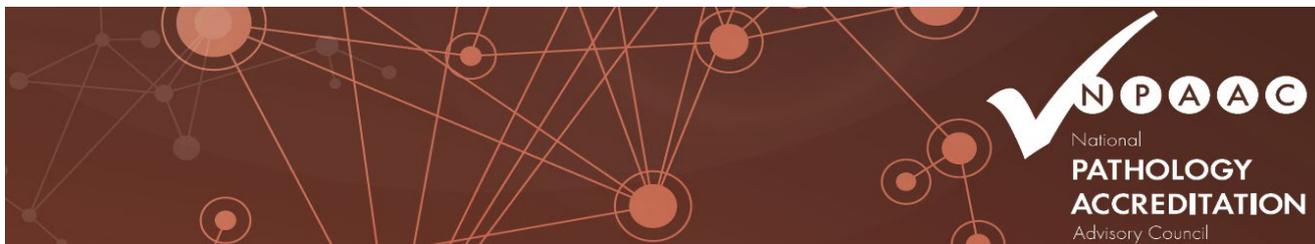
Q. What is Scope of Practice and credentialing body?

The aim of the Supervision Requirements is to ensure there is an appropriately qualified, and competent pathologist (or for Category S and M laboratories, a relevant medical practitioner) with a relevant scope of practice for the testing that is being supervised.



Scope of practice and credentialing body are defined in the Supervision Requirements.

The designated person for all medical laboratories, including Category S laboratories, will need to be able to provide assurance to the accrediting agency that they have the scope of practice appropriate to the range of testing that they supervise and that this will need to be verified by a relevant credentialing body.



Q: What is the role of Clinical Scientists in the supervision of pathology testing?

The *Requirements for Supervision in Clinical Governance of Medical Pathology Laboratories* does not prescribe the role description of any member of the pathology workforce. Its purpose is to make clear the personal accountability of the registered medical practitioner for testing within their scope of practice.

It is recognised in the Standard (refer to the Introduction) that “ the provision of quality pathology services relies on the collaborative working relationship between Pathologists, Clinical Scientists, Scientist, Technicians and other laboratory staff.” and that “The Designated Person must make risk based decisions about the provision and supervision of tests based on the complexity of the tests performed , the number of tests performed, the qualifications and experience of scientific staff and the level of pathologist supervision required.”

It is not expected that there will be any diminution in the important role that Clinical Scientists play in the provision of pathology services or direct supervision of pathology testing.

Q: Can a scientist with RTAC qualification supervise genetic testing?

An RTAC qualified scientist who wishes to extend their scope of practice to supervise genetic testing would be expected to have a clinical scientist qualification and competency pertaining to genetic testing.

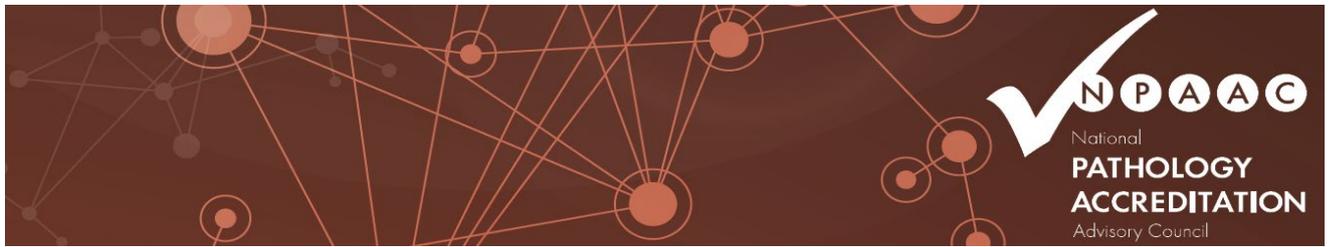
Q: Why have there been changes to S laboratory category?

The intention of the Category S laboratory category was to define specialised medical testing carried out by persons with specific expertise in a limited range of tests for a particular target population. Over time routine testing has increasingly been carried out in S laboratories. This has given rise to differences in the supervision arrangements for the same test in Category GX/ GY/ B laboratories and S laboratories. The revised Standard seeks to restore the original purpose of the Category S laboratory. It is expected that this is testing which is not available in standard pathology laboratories to address a need in a small number of patients under the supervision of a medical practitioner with specific expertise in this area.

It is expected that testing that is currently considered “specialised” will also become routine pathology testing in the future and will not be eligible for a Category S laboratory classification.

Q: To which laboratory category is POC testing to be assigned?

For the purposes of supervision, POC testing may be provided by a Category B laboratory (providing PoCT services only - S3.10) where the *designated person* for the pathology service is a pathologist, or a Category M laboratory, where the *designated person* is another medical practitioner.



Q: What is considered to be *normal working hours*?

Normal working hours are considered to be hours during which the laboratory is operating and during which supervision needs to be provided onsite.

It should be noted that access to Pathologists for consultations may need to be provided outside of *normal working hours*.