

Guideline

Subject:	Fellows as Assessors for NATA/RCPA Accreditation
Approval Date:	March 2005, November 2005, March 2008, November 2009, November 2013, April 2015, March 2018, September 2019, January 2020, April 2022
Review Date:	April 2026
Review Committee:	BPPQ
Number:	1/2005

Assessors should identify the roles of the pathologists, clinical and senior scientists and senior managers in the organisation and assess how well they are performing those roles. Appropriate laboratory supervision requires a clearly documented and understood governance structure that ensures that all testing is supervised by persons who are appropriately qualified, competent and operating within their Scope of Practice and who are accountable to the Designated Person.

- Assessment should involve all pathologists, not just the supervising pathologist, as well as clinical and senior scientists and managers.
- Any findings needing to be addressed as requirements for accreditation need to be aligned to a relevant clause in the accreditation requirements and must be recorded with suitable evidence. Remember accreditation is the requirement of a facility to meet minimum acceptable standards. An assessment of the level of risk posed by nonconformances will be required for the assessment report to the organisation.
- It is also reasonable to identify areas of concern and/or continual improvement which may not breach published accreditation criteria but are certainly worth recording. These may be a more stringent standard than that required for accreditation but can be included in the assessment report as observations, comments or recommendations. It is still useful to obtain evidence if possible. However, the facility may not necessarily be required to address these.
- The issues raised in an assessment report should be discussed with the pathologist(s) in the facility prior to the exit meeting at the conclusion of the assessment visit. This will hopefully negate any misinterpreted information being presented.

Essential roles are those that pathologists are primarily responsible for, or are expected to take a leadership role in.

The checklist below is derived from, and builds on, the NATA Assessor Record Sheet, and includes other points appropriate for discussion with pathologists at assessment visits.

RANGE OF WORK

(Ref: ISO 15189:2012 4.1.2.2, 4.1.1.4 & 4.1.2)

- Is the range of testing appropriate? If not, should tests be reviewed, numbers reduced, tests extended etc? How are pathologists involved in these decisions?
- What clinical activities is the pathologist involved in that relate to the laboratory?
- How much time does the pathologist spend in the laboratory as opposed to doing administration, clinical duties, research etc?

WORK REFERRED

(Ref: ISO 15189:2012 4.5)

- Are referral arrangements satisfactory?
- What criteria are used to determine that a specimen is difficult and warrants referral?

- Are reference laboratories being monitored for service quality?
- Check a specific example of a referred test specimen – how was it handled?

REJECTION OF UNSUITABLE SPECIMENS

(Ref: ISO 15189:2012 5.4.6 & 5.8.3.1)

- Are the criteria for determining unacceptable/unsuitable specimens (including minimum labelling requirements) documented?
- Is the policy on the handling of these specimens appropriate?
- Is a comment regarding the unsuitability of a specimen included on the report?

ETHICAL TREATMENT OF SPECIMENS

(Ref: ISO 15189:2012 4.1.1.3)

- Are policies and procedures available to ensure that staff treat human samples, tissues or remains with due respect?

METHODS

(Ref: ISO 15189:2012 5.5.1.1 & 4.15.2 a & 5.5.1.4)

- Are appropriate staff/pathologists involved in method review?
- Has Measurement Uncertainty (MU) been estimated for all those tests that are performed by the laboratory where MU applies? Are the MU estimates reviewed and what is the frequency of these reviews?
- Has the pathologist played a role in this?
- Have all In-House IVDs or modified commercial assays been appropriately validated, approved by a pathologist and registered with the TGA?

METHODS MANUAL

(Ref: ISO 15189:2012 5.5.2)

- Are biological reference intervals or clinical decision values included?
- Is the source of the laboratory's biological reference intervals documented?

RETENTION OF RECORDS

(Ref: ISO 15189:2012 4.13 and NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021))

- Are records (i.e. primary data, final reports) retained according to minimum NPAAC retention times?

REPORTS

(Ref: ISO 15189:2012 5.8.2 & 5.8.3 and Medical Testing Field Application Document)

- Do reports include date/time of issue, reference intervals, comments on results?
- Do reports bear appropriate authorisation by a pathologist?
- Are reports expressed in current terminology?
- Are the comments included on test reports appropriate?
- Are appropriate follow-up procedures for test results in place?
- Are the biological reference intervals quoted on reports relevant to patient's age, sex and, where relevant, pregnancy status?
- How does the laboratory ensure confidentiality of patient information?
- How are electronic reports generated?
- How does the facility ensure electronic reports are reproduced accurately by the information system external to the laboratory intended to directly receive the information?
- How is the facility's process for automated selection and reporting of results (including the presence of sample interferences) verified or validated?

EQUIPMENT

(Ref: ISO 15189:2012 5.3.1)

- Is the equipment in use appropriate? Is it being maintained appropriately?
- Is equipment maintained in accordance with manufacturers' instructions? Are microscopes ergonomically sound?
- What role do pathologists have in determining equipment acquisition?
- Is there a defined procurement process for new equipment?

INTERNAL QUALITY CONTROL

(Ref: ISO 15189:2012 5.6.2, NPAAC Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018) and Medical Testing Field Application Document)

- How is the pathologist personally involved in internal quality control activities?
- Are results recorded and reviewed and corrective action reports produced?
- Where QC falls outside specific criteria is there a process to halt testing and/or retest specimens already processed?
- Does the process include recalling and reissuing results where necessary?
- Does the laboratory have a system of long-term monitoring of internal quality control results which assesses method performance?

EXTERNAL QUALITY ASSURANCE

(Ref: ISO 15189:2012 5.6.3, NPAAC Requirements for Quality Control, External Quality Assurance and Method Evaluation (Sixth Edition 2018) and Medical Testing Field Application Document)

Please note: Assessors should ask if the laboratory/pathologist is participating in the external QAP for assessment of the quality of testing in the laboratory or purely for education purposes. If it is purely for education purposes, the assessor should not include performance in these QAPs as part of the NATA/RCPA assessment process.

- Does the laboratory participate in external quality assurance programs (QAPs) covering its full range of testing?
- What role do pathologists play in external quality assurance programs?
- Do the records show evidence of review and by whom?
- Do the records show what corrective action has been taken where necessary?
- Does the review include an assessment of the impact caused on patient samples for outlying QAP results?
- Are the QAP records kept in accordance with NPAAC minimum retention times?

NUMBER OF STAFF (Workload)

(Ref: ISO 15189:2012 4.1.1.4 & 4.1.2.1)

- Are staff/pathologist numbers and qualifications appropriate and adequate from a workload perspective?
- Are pathologist numbers adequate to train the number of trainees the department has?
- Are the duties and responsibilities of each staff member/pathologist documented?
- Are arrangements adequate in the event of staff/pathologist absences?

SUPERVISION/CLINICAL GOVERNANCE ACTIVITIES

(Ref: ISO 15189:2012 4.1.1.4, 4.1.2.1 & 4.1.2.5 & NPAAC Requirements for Medical Pathology Services (Third Edition 2018) & Requirements for the Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021))

- Is the clinical governance structure clearly defined and documented?
- Has a risk assessment of supervision arrangements been performed?
- Is every test supervised by a pathologist with relevant scope of practice? Scope of practice is the discipline and/or areas of testing in which a person has been trained and successfully examined, or assessed as competent, by the College and in which they have met current Continuing Professional Development and recency of practice requirements. Areas of testing for each discipline are outlined in the discipline-specific Trainee Handbooks. Technical assessors are encouraged to consult the relevant Trainee

Handbook if concerns about scope of practice arise.

- How many staff does each pathologist supervise? How many trainees?
- Is the level of supervision by the pathologist in charge appropriate for this category of laboratory? Is the clinical input adequate for specific disciplines? Are there adequate arrangements for supervision in the absence of the pathologist in charge? Are out of hours arrangements adequate in terms of supervision?
- How are pathologists involved in decision making / policy formation regarding staffing classifications, performance reviews, staff education?
- What role do pathologists play in regard to provision / supervision of consultation and interpretation of pathology results and reports?
- Is the pathologist involved in the supervision of branch or off-site facilities?
- What input does the pathologist have in this supervision? What interaction is there with clinicians and how is this documented?
- If the pathologist works in isolation, what measures are being used to ensure professional support and maintenance of up to date skills?
- Does the laboratory meet NPAAC supervision requirements?

COMMUNICATION WITH PEERS

(Ref: ISO 15189:2012 4.1.2.6 & 4.7)

- Are the procedures for important communications documented e.g. procedures for obtaining expert opinions, amending reports?
- Are staff and pathologists aware of these procedures?
- What is the process for review of these procedures?
- Are interactions with clinicians documented e.g. provision of advice when no access to patient record, records of cases presented at multi-disciplinary team meetings?
- Are pathologists involved in Peer Review?
- Is professional mentoring available for the pathologists?

CONTINUING EDUCATION

(Ref: ISO 15189:2012 5.1.2, 5.1.5 & 5.1.8 and NPAAC Requirements for Medical Pathology Services (Third Edition 2018) & Requirements for the Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021))

- Have all pathologists and clinical scientists met continuing professional development requirements applicable to their scope of practice?
- What conferences, scientific meetings have pathologists attended since the previous accreditation visit?
- If a pathologist is working in a different discipline from the one in which they trained, what training have they done to gain and maintain expertise in this area?
- Are pathologists who work in across a number of disciplines able to demonstrate appropriate continuing education in those areas?
- What continuing education has been undertaken by pathologists who work part time or have been away for significant lengths of time to maintain currency?
- Does the pathologist consider that he/she might need more training? If so, in what areas? Is training available e.g. post-Fellowship diplomas?
- What other training has been undertaken e.g. in management? Informatics?
- In what ways are the pathologists participating in education for staff / trainees?

OH&S

(Ref: ISO 15189:2012 5.2.2)

- Do the pathologists have a leadership role in this area?
- Does the laboratory have relevant written safety procedures?
- Are all staff instructed in safety procedures?
- Is the safety equipment held by the laboratory appropriate?
- Are laboratory surfaces (e.g. benches, shelves) and equipment (e.g. centrifuges, refrigerators) disinfected?

- Are bio-hazardous materials disposed of safely?
- Are staff offered appropriate immunisation?

TRAINING FOR FELLOWSHIP RCPA

(Ref: ISO 15189:2012 5.1.5)

- Are the trainees happy with the training they are receiving?
- Are the supervisors happy with their ability to deliver training?
- Is there adequate supervision for the trainees?
- Are there regular formal education sessions provided?
- Do the trainees have library and internet access?
- Is the physical environment ie equipment and floor space satisfactory?

OTHER ISSUES

- Are there any other points that the pathologists / assessor believe are relevant?