Sullivan Nicolaides PATHOLOGY
Quality is in our DNA

The role of the College Fellow as a NATA/RCPA assessor

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Medical Testing Accreditation - Process

- All pathology laboratories must maintain accreditation to be eligible for Medicare reimbursement
- Assessments at *least* once each 2 years

– Full assessment team each 4 years + Nata staff officer each 2 years in between.

– Higher frequency for “selected” labs

– Additional visits if any major change in technology, senior staff, new methods

– Alternate surveillance program for high performing labs

NATA Accreditation Process

- **Laboratory operates its own Quality System/Technical Standards**
  - compliant with NPAAC Requirements
- **Laboratory submits relevant paperwork to NATA**
  - NATA performs Desk Audit
- **On-site laboratory accreditation visit**
  - Minimum 3 assessors per Laboratory “Section”
  - NATA Staff Officer, Pathologist, Scientist
  - Detailed vertical and horizontal audit – “sampling exercise”
  - Guided by professional judgement of Assessment Team
  - Exit interview
- **Detailed Accreditation Report prepared**
  - Due process and transparency
  - MTAAC expert “Review Panel” to consider and arbitrate

Outcome of NATA Accreditation

Detailed accreditation report

- **Conditions**: Must be addressed as a condition of accreditation
- **Minor Conditions**: Should be addressed, but could carry over till next accreditation visit
- **Observations**: Suggestions for improvement; tags for future assessments
- Reports are intended to be educative as well as a compliance tool
- Due Process: Lab can respond to any point, either by compliance, correction or to argue the case

Medical testing Accreditation 2015 snapshot

- 763 accredited sites
- 40 new sites pa
- 133 Category G, 300 Category B and 207 Category S labs, 11 Category M
- Around 400 assessments pa
- 50 surveillance visits
- 6 suspensions
- 1000 assessors (Pathologists & scientists)

NATA File Audit: common causes of accreditation failure

- inadequate QC limits and review procedures,
- limited QAP results, no/inadequate review of QAP,
- no/inadequate corrective action taken to out-of-range QC and QAP results,
- no/inappropriate verification and validation studies

Accreditation deficiencies

AACC Better health through laboratory medicine.

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Top Laboratory Deficiencies Across Accreditation Agencies

Problems with documenting personnel competency top the list

Author: Seetharam Chittiprol, PhD, DABCC, Joshua Bornhorst, PhD, DABCC, FAACC and Frederick L. Kiechle, MD, PhD, FAACC

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Topics: Lab Management, Government and Regulatory, Quality Assurance, Patient Safety, CLIA Regulations

Clinical laboratories in the U.S. operate within a complex regulatory system that monitors the accuracy and quality of testing. Laboratories must be familiar with the regulatory process and the agencies that inspect and accredit laboratories in order to meet quality guidelines, maintain inspection readiness, and ensure their staff understand and follow

RMPS personnel

- **6. Personnel**
  S6.1 There must be sufficient medical, scientific, technical and support staff who have the qualifications, training and competence to provide Medical Pathology Services consistent with the scope of accreditation.
- C6.1(i) Laboratories **must** ensure an **appropriate scope of practice for Pathologists and Clinical Scientists** for the scope of testing performed in the Medical Pathology Service and maintain such documentation.
- C6.1(ii) All qualified staff involved in the provision of Medical Pathology Services **must** provide documented evidence of participation in continuing professional development commensurate with their role and responsibilities.
- C6.1(iii) Staff **must** undertake relevant professional activities to enable them to maintain and update the skills required to undertake their individual responsibilities.
- C6.1(iv) Where maximum workload measures are specified in technical documents, these **must** not be exceeded.
- C6.1(v) Medical and scientific staff **must** participate in relevant peer review and assessment processes.
- C6.1(vi) Medical Pathology Services **must** provide sufficient time and support for staff to undertake relevant professional development activities.

RMPS Risk assessments

- **Appendix A Risk Assessment – Risk Points**

1. Governance: Clear governance structures will facilitate prompt corrective action where the accuracy, clinical utility or timeliness of testing has been compromised. They will also promote early notification to the referring doctor about test results or clinically significant events in the management of the patient.
2. Competency of staff: Demonstrated ability to perform a task successfully and efficiently.
3. Patient identification: Clear processes to allow unequivocal identification of the patient and promotes safe and timely testing.
4. Specimen integrity: Processes that address common pre analytical issues, in particular specimen haemolysis, and promote safe and timely testing.
5. Specimen traceability: Processes that enable the traceability of samples and promote the safety and timeliness of testing.
6. Specimen analysis: Processes that address failures of Quality Control and promote safe and timely testing.
7. Verification, validation and documentation of methods: Verification is the process of demonstrating the performance criteria to which the method has been validated can be met by the facility, prior to introducing into routine use. Method validation is the process of establishing the performance characteristics and limitations of a method, and the identification of the influences that may change these characteristics, and to what extent.
8. Quality Assurance: Participation in Quality Assurance Programs, performance reviews and corrective actions where performance is unsatisfactory.
9. Reporting results: Unambiguous reports, current best practice reporting, promote the safety of testing by facilitating timely and appropriate clinical interventions.
10. Turnaround times: Turnaround times that allow timely decision-making promote good patient outcomes from testing.
11. Communication: Processes that allow the communication of critical (high risk) results to clinicians, the management of confidential results, and privacy, promote the safety of testing.
12. Send away tests: Risk management processes that address transport, handovers, specimen integrity, the quality of testing in the referral Medical Pathology Service, turnaround times and the delivery of reports to the referring doctor and the referring Medical Pathology Service improve the safety of testing.
13. Reviews of incidents: Processes that investigate incidents with real or potential adverse outcomes for patients, take corrective actions, monitor the efficacy of these actions, and improve the safety of testing. Processes to identify, track and reduce diagnostic errors.

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 1**

Assessors should identify the roles of the pathologists, senior scientists and senior staff managers in the organisation and assess how well they are performing those roles.

- Assessment should involve all pathologists, not just the supervising pathologist, as well as 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.**
- In addition 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.

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 2**

- The checklist below is derived from, and builds on, the Assessor checklist, and includes other points appropriate for discussion with pathologists at assessment visits.
- **RANGE OF WORK**
- 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?

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 3**

WORK REFERRED

- 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

- 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?

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 4**

ETHICAL TREATMENT OF SPECIMENS

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

METHODS

• 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 and approved by a pathologist?

METHODS MANUAL

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

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 5**

RETENTION OF RECORDS

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

REPORTS

• Do reports include date/time of issue, reference intervals, comments on results?
• Do reports bear a legible signature or appropriate authorisation?
• 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 does the facility process for the automated selection and reporting of results (including the presence of sample interferences) is verified or validated?

EQUIPMENT

- 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?

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 7**

INTERNAL QUALITY CONTROL

• 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

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?

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 8**

NUMBER OF STAFF (Workload)

• 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 / MANAGEMENT ACTIVITIES

• 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?
• Does the laboratory meet NPAAC supervision requirements?
• 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?

Guideline: **Fellows as Assessors for NATA/RCPA Accreditation 9**

COMMUNICATION WITH PEERS

• 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?

CLINICAL GOVERNANCE

• Who does what and who is ultimately responsible for what?
• What interaction is there with clinicians and how is this documented?
• How is responsibility delegated and what is the process for formalising this?
• If the pathologist works in isolation, what measures are being used to ensure professional support and maintenance of up to date skills?

CONTINUING EDUCATION

- 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 for 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

- 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

- 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?

Major issues during assessments

- Supervision
- Competency assessment
- Validation/verification
- QC performance
- QAP follow up
- Audit program
- Documentation