Quality Managers Forum

Tuesday 24 & Wednesday 25 June 2014

CHANGES TO MEDICAL TESTING ASSESSMENT MODEL

Andrew Griffin
Deputy Sector Manager – Life Sciences

What will be covered

- The assessment model
- Benefits of proposed model
- Visit dates
- Visit types

The Medical Testing Assessment model

Began 1 July 2013

New accreditations

- 2 year cycle
  - Surveillance visit at 12 months post initial assessment
  - Reassessment at 24 months post initial assessment

  - If facilities meet accreditation requirements at 2 year reassessment then moved on to the 4 year cycle

The Medical Testing Assessment model

Existing accreditations

- 4 year assessment cycle to include
  - reassessments once per cycle (refocus on technical criteria of the standards)
  - surveillance visit once per cycle (primarily review management system criteria)
    - to be scheduled at 2 year mark post reassessment
  - on-line audits of targeted information (using NATA website Portal)
    - based on assessment history / previous findings / selected data
    - to be schedule at 12 and 36 months

The Medical Testing Assessment model

- Single discipline facilities will have 2 online audits, 1 Surveillance visit and 1 Technical visit
- Multiple discipline sites
  - may have a technical visit all at one time over a period of days or weeks, one surveillance visit over days but no more than 1 week and 2 online visits
  - or staggered technical visits throughout the cycle, one surveillance visit over days but no more than 1 week and 2 online visits
- Should only have one Surveillance visit for each site not a surveillance visit per discipline – dependent on whether the QMS is uniform across the site
  - If not may have multiple Surveillance visits
- Corporate surveillance model available for multisite organisations who meet documented criteria

Corporate assessment model – for multi-site organisations

- Certain performance criteria must be satisfied for these visits to occur
  - A demonstrated uniform quality management system across all sites
  - A sound assessment history and stability in senior management/ownership
  - An undertaking that any weaknesses identified at one site will be investigated across all sites in the group (where relevant)
  - Notification to NATA (14 days in accordance with NATA's Rules) of any significant staff, testing and accommodation changes

- Policy Circular 46 gives further information on the Corporate Surveillance model

Corporate assessment model – for multi-site organisations

- Short notice visits – 10 days
- A full reassessment of main site and larger sites within organisation
- Full reassessment of certain disciplines e.g. Histology, Cytology
- All sites receive a surveillance visit (2 years)
  - Main site full management system review
  - Satellite sites – confirmation of implementation across corporate sites
- Partial technical visit to satellite sites (branch) focusing on a specified discipline
- All sites receive a technical visit but not every discipline at every site
  - i.e. not all sites will be assessed for every discipline
  - Sampling the scope
- Information for all sites will be requested for the online activity but will be linked to the main site(s)

Plan for Applicant facilities:

	Month 0	12	24
ADV	ASS/RES	SRV	RES

Plan for established facilities post initial RES at 24 Months, which is Month 0 in this model:

Month 0	12	23 (22 – 24)	36	46 (44 – 48)
RES	DTR	SRV	DTR	RES

ADV – Advisory visit
ASS – Initial assessment – full reassessment
DTR – Desk top review – online submission
RES – Reassessment (or partial reassessment)
SRV – Surveillance visit – staff officer visit

Benefits of a proposed model

- Increased contact with laboratories – annual contact
- Reassessments refocused to concentrate on review of technical requirements with increased support from the NATA lead assessor for the technical assessors
  - the latter will allow greater consistency in application of requirements by closer “supervision” of the assessment team
- Surveillance visit allows for concentrated review of QMS and targeted technical activities
- Targeted and risk based approach on the review of laboratory performance for the on-line / desk-top audits to be introduced
- Decrease in use of technical assessor resources i.e. 3 year to 4 year RES
- Minimal change to organisations currently on the “Corporate Surveillance” model with continuation of scope sampling & partial technical visits

Benefits of a proposed model

- Proposed model is in keeping with the 2008 pathology sector stakeholder feedback
- Allow for NATA/RCPA program to be recognised by ILAC / APLAC MRA

- Pick up trends and issues earlier
  - persistent poor performance
  - changes to ownership and governance
  - lab closures

Visit dates

- July – September – Reassessment
- October – December – Surveillance visit
- January – March – Reassessment
- April – June – Surveillance visit
- Until all sites are on the new cycle
- On-line activity starts 1 July 2014

Visit types

Initial assessment – no change

- 8 weeks from receipt of application and supporting information

- Purpose
  - to conduct a formal review and to determine compliance with the accreditation requirements
    - both quality management system and technical requirements of the relevant standards are assessed in full

Surveillance visit – new to Medical Testing

- 24 months

- Purpose
  - review continuing compliance with the accreditation requirements
    - focus is on full assessment of **the quality management system** (including a document review of the Quality Manual)
    - selected elements of the technical requirements will also be conducted
      - e.g. summary QAP data

Reassessment – re-scoped visit type

- 48 months

- Purpose
  - review continuing compliance with the accreditation requirements
    - focus is on full assessment against the technical requirements of the standards
    - limited review of the quality management system will also be conducted
      - e.g. review of last internal audit, management review etc

On-Line Surveillance – new activity type

- At 12 and 36 months

• Purpose

- review ongoing compliance with accreditation requirements
  1. based on its assessment history
     - focus on issues which were identified at the last on-site visit
  2. may also review additional records on a case by case basis and dependent on risk
     - e.g. QMS and technical data such as management reviews, validation data of new assays, staff and test changes, QAP enrolment, participation and performance

What will you need to submit?

CHANGES TO FACILITY

Any significant changes to your facility NATA has not previously been advised of since your last assessment / visit.

Changes include, but are not limited to, ownership, key staff, equipment, test methods, new assays and analytes

ADDITIONS TO THE SCOPE OF ACCREDITATION

Additions to the Scope of Accreditation may be considered as part of a separate chargeable activity.

PREVIOUS ASSESSMENT FINDINGS

- Implementation of corrective action taken to conditions raised at the preceding on-site visit (surveillance or technical assessment) for all Minor Conditions for the sites falling under the OLS

- Confirmation of action taken, and date Minor condition(s) closed with evidence

- If not closed, provide timeline for closure of condition and reason for non-closure and evidence to date

No requirement to submit information regarding Major Conditions (C) from the previous on-site visit as these are already closed out

Failure to close out Minor Conditions within 12 months may result in a follow up technical assessment visit

MANAGEMENT SYSTEM

- **significant changes to your documented management system since the last assessment visit**

- **If the amendment records from your facility's Quality Manual and/or associated procedures provide adequate information these may be substituted.**

REVIEW OF MANAGEMENT SYSTEM

- Information on the QMS generated since the last On-site visit:

- Lead assessor to advise of what is to be submitted
- Management Review records since (date of last on-site visit)
- Current Internal Audit schedule
- Summary of Internal Audit findings and trend analysis
- Summary of nonconformities identified and actions taken
- An example of a specific non-conformance record
- Summary of complaints, action taken and trend analysis
- Evaluation of Referral arrangements
- Evaluation of consultants
- New or amended Quality Objectives and their measurement
- Quality indicator target achievement analysis
- Assessment of user feedback

REVIEW OF TECHNICAL ACTIVITIES

5.1 Personnel

- Records for new supervisory staff (CVs, training, competency assessment)

As indicated in Section 1

- Records of supervisory visits (to Cat B labs) including time spent on site and details of activities undertaken;

5.2 Accommodation and environmental conditions

- Details of any significant changes to accommodation as described in Section 1

REVIEW OF TECHNICAL ACTIVITIES

5.3 Laboratory equipment, reagents and consumables

- New equipment: records of acceptance testing, final summary of results and evidence of formal authorisation as fit-for-purpose
- Sample of equipment maintenance records since the last on-site assessment
- Sample of verification records for equipment that has been previously been found to be defective and has since been returned into use.
- Sample of Blood Storage Refrigeration maintenance records for on-site and off-site equipment

5.4 Pre-Examination processes

- Site audits of AS/NZS 4308 collection sites

REVIEW OF TECHNICAL ACTIVITIES

5.5 Examination processes

- Verification summaries for examination procedures introduced since last on-site visit

- Details of reference intervals and clinical decision values that have been amended, along with evidence of verification of the reference intervals/clinical decision values

- Full validation reports for ALL NEW Class 3 and 4 In-house IVDs introduced since the last assessment

- Summary validation reports for ALL NEW Class 1 and 2 In-house IVDs introduced since the last assessment

REVIEW OF TECHNICAL ACTIVITIES

5.6 Ensuring quality of examination results

- Annual participation certificates for all QAP
- QAP reports for Histology, Gynaecological Cytology and Immunohematology
- Lead Assessor to list other QAP EoC or KPI reports to be submitted on a sampling basis but will cover all disciplines
- Performance measures for Gynaecological Cytology
- Evidence of review of QAP
- Details (or summaries) of action taken where predetermined performance criteria are not fulfilled

REVIEW OF TECHNICAL ACTIVITIES

- **5.8 Reporting of Results**
- **Changes to report formats including any new or modified tests not previously assessed.**

- **5.9 Release of Results**
- **List any tests that have been selected for automated reporting since the last on-site visit AND any auto-validated tests with changed parameters e.g. reference intervals, critical limits.**

- **For these tests, evidence of validation for proper functioning must be submitted as requested.**

- **5.10 Laboratory information management**
- **List any changes to the LIS since the last on-site visit e.g. newly interfaced items of equipment, system upgrades or middleware changes.**
- **Evidence of verification of changes to the LIS including evidence of formal authorization as fit-for-purpose to be supplied as requested**

Questions?