NATA Members Meetings

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CHANGES TO MEDICAL TESTING ASSESSMENT SURVEILLANCE

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Overview of discussions

- Reasons for a proposed revised surveillance model
- Considerations for the revised model
- Proposed model
- Benefits of proposed model
- Visit types for the proposed model
- Next steps

Reasons for a new surveillance model

Stakeholder feedback

- In 2008 NATA entered into a round of stakeholder engagement activities to consider key issues, one being the existing 3 year surveillance / assessment model
- A number of key areas were identified consistently, these included
  - **the model of three yearly surveillance periods alone on a site by site basis is considered outdated and should be reviewed to better reflect laboratory operations**
  - **there may be other ways of assessing compliance which may complement the traditional full assessment visit type of audit**
  - **more, rather than less, interaction between NATA and laboratories would be a way of achieving this**
  - **the accreditation model should be more holistic and based on a risk analysis approach and be involved in complete processes – Preanalytical, analytical and post analytical**

Reasons for a new surveillance model

- **Flexible approach - to consider the organisations business practices**

- pathology accreditation is still a valuable tool for ensuring ongoing technical competence
- still relevant to contemporary laboratories

- Subsequent correspondence with key stakeholders RCPA, Medicare and NPAAC and member organisations confirms the points identified above are still relevant and should be progressed
- Especially more frequent contact and ability to identify issues earlier

New model to consider requirements of ISO 17011– Accreditation Bodies International Standard - Mutual Recognition Agreement (MRA)

- There needs to be a site visit at least once every 2 years (not full reassessment)
- Technical assessment at least every 5 years
- Benefit is that it should provide added reassurance to both federal and state agencies regarding the program's operational processes and outcomes
  - i.e. is recognised internationally

Considerations for a revised model

- The same level of technical rigour is to be maintained for the conduct of assessments
- Pick up serious competence issues earlier
- Same peer review process – technical assessors
- Minimal additional resources to be required
- Minimal or no additional costs be imposed on members
- Adopt a flexible client focused approach for multi-site organisations (accommodation of the existing alternative surveillance model)
- Discipline/ directorate based approach if appropriate
- Site based if appropriate
- The complete test cycle, including pre-analytics, analytics and post analytics to be assessed
- Other forms of surveillance activity to be considered apart from routine full reassessments
  - partial technical visits, surveillance visits, on-line and virtual activities (PoCT??)

Considerations for a revised model

- NATA widely have a 3 year reassessment cycle
- With 18 month surveillance visit

- Obvious approach to adopt the NATA model in MT
- would not reduce assessor resource requirements as we already have a 3 year cycle
- Simply add an extra visit at the Midway point
  - Double NATA staff resource requirements

Proposed model

- 4 year assessment cycle to include
  - reassessments once per cycle (refocus on technical criteria of the standards)
  - surveillance visits (primarily review management system criteria)
    - to be scheduled mid cycle
  - off-site / 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

Proposed model

- Single site organisations will be straight 2/4 year model
- revised model is to accommodate (with minor revision) a corporate assessment model currently in place for some multi-site organisations
- Extend further to organisations who meet certain criteria
- Ensure process is transparent
- Cycle based on corporate structure in consultation with laboratory management

Corporate assessment model – for multi-site organisations

- For such visits it must be ensured corporate procedures are in place across the whole organisation
- Non-corporates and deviations in procedures across sites will render this type of activity unavailable and a full reassessment would be required
- 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

Corporate assessment model – for multi-site organisations

- Short notice visits – 10 days
- A full reassessment of main site and larger sites within organisation (hubs?)
- 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

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
- 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
- Model has been discussed with and supported by MTAAC, RCPA, NPAAC and Medicare Australia

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

Visits types for the proposed model

Initial assessment – no change

- 12 weeks from advisory visit

- 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

Desk top review – new visit type

- 12 and 36 months

•Purpose

- a 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

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

Regulatory impact

- What impact will the new model have on DHS – Medicare Report on Premises
  - Currently released every 3 years in line with assessments.
  - Probably be changed to fit the RES i.e. every 4 years
  - Can always bring if back if issues are identified
- Impact on Medical Testing FAD

Next steps

- Surveillance roll-out 1 July 2013
- Existing next due date remains as is
- Roll out planned as next visit falls due
- July – September – Reassessment
- October – December – Surveillance visit
- January – March – Reassessment
- April – June – Surveillance visit
- Until all sites are on the new cycle
- On-line visit starts 1 July 2014

Questions?