27th MEETING OF MEDICAL TESTING ACCREDITATION ADVISORY COMMITTEE

Held 13 September 2017 at PARKROYAL Melbourne Airport

SUMMARY

Meeting Summary

1) NPAAC

NPAAC was invited to provide a brief summary of NPAAC activities, including the provision of some clarification regarding the proposed revised *Requirements for Supervision in Clinical Governance of Medical Pathology Laboratories*.

NPAAC advised that they have adopted a risk based approach with the accreditation standards, including the new draft *Requirements for Supervision in Clinical Governance of Medical Pathology Laboratories*.

These new requirements are expected to be published as soon as possible with a 6 month transition period and a guide to be developed.

It was noted that the proposed transition period is to provide laboratories sufficient time to make necessary arrangements before the requirements come into effect.

It was noted that NPAAC is exploring educational tools, such as webinar and podcasts on the proposed revised Requirements.

2) Review of Assessment Cycle

The 4 year assessment cycle commenced on 1 July 2013. As one full cycle has now been completed, a review of the effectiveness of the cycle has been initiated.

The scope of the review will include:

- analysis of findings between poorly performing and well performing laboratories, taking into account the grading of findings and issues identified;
- mapping of non conformances to ISO and NPAAC standards and analysis of this data to identify any trends;
- recommendations for further refinement of the accreditation process including effectiveness of on-line activities; and
- potential for continued development/application of a risk assessment tool.

3) Risk Assessment

Standards writing bodies such as ISO and NPAAC have recognised the need to produce more risk based rather than compliance based standards.

As part of its routine accreditation processes, NATA already classifies assessment findings based on risk of the laboratory activities to patient safety. A number of factors are considered when determining the risk level:

- significance of each finding and their subsequent coding i.e. C, M or O;

- number and nature of the finding(s) for the laboratory as a whole (this also determines the coding);
- the impact of findings on patients' results and hence the safety of patients;
- past assessment history and ability to rectify issues;
- the professional judgement of the assessment teams; and
- any follow up with the Accreditation Advisory Committee and the RCPA.

Pre-analytical error is recognised as a common concern and NATA has formed a working group to determine the depth and robustness of the pre-analytical component of assessments.

Clinical Governance assessments

A number of assessments specifically looking at clinical governance have been performed. These visits have identified that clinical governance requires more scrutiny during the assessment process.

These focused assessment will continue to be trialed for selected networks before being formalised.

4) TGA IVD Regulations

The TGA IVD regulations were fully enacted on 1 July 2017 to include in-house IVDs. The IVD regulations now require all commercial diagnostic testing to be included on the Australian Register of Therapeutic Goods and all Class 1 - 3 In-house testing are to be NATA/RCPA accredited.

Should any in-house testing not be accredited on each 1 July deadline it cannot be offered thereafter until accredited. All new In-house IVD s Class 1 to 3 must be notified to TGA by 1 July each year.

The TGA and NATA have a MoU in place which allows for the exchange of information which has proven to be very valuable to both parties.

Committee membership

Dr Raymond Chan, RCPA Liaison officer and A/Prof Gus Koerbin's terms expire in March 2018. Advice from RCPA and AACB respectively will be sought for replacements.

Post Meeting note: Both members' terms have been extended.

Next meeting

The next meeting is scheduled for Tuesday 31 July 2018.

Andrew Griffin

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Secretary, Medical Testing Accreditation Advisory Committee