



National Association of Testing Authorities, Australia

## MEETING OF MEMBERS' REPRESENTATIVES ON NATA COUNCIL

9 May 2013

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### SUMMARY OF KEY ISSUES

- **Assessment Effort Process**

Assessment of activities, covered by the scope of accreditation, is based on a sampling approach for each competency area. Competency areas have been defined for each field and program. For each assessment a sampling plan developed by NATA is confirmed with assessment team to ensure adequate coverage of all competencies under the scope of accreditation (for further detail, refer to NATA Info Paper 8).

- **Reformat of the NATA Accreditation Publications**

NATA has revised and issued the accreditation publications on the NATA website including the accreditation criteria and guidance information. The purpose of the restructure was to ensure: consistent accreditation application process across fields / programs; consistent expression of relevant NATA criteria applicable to all fields / programs; and consistent guidance for equipment check and calibration intervals.

- **Format of scopes of accreditation**

A project is currently in progress to review the format (presentation) of scopes of accreditations (SoAs). The project is aimed at introducing a “uniform format across all fields and programs”, improving the search function on the NATA website and to ultimately allow in the future one scope to be issued per facility which may be accredited in more than one field and/or program. SoAs to be presented in tabular format with fixed columns (mandatory information) and optional columns (dependent on specific industry, regulatory or member needs).

- **Other Developments**

*Accreditation of branch sites*

Policy (PC 42) was published in February 2013. Allows a facility to claim accreditation for a new branch site established under its control prior to the new site gaining accreditation in its own right.

*Asbestos counters / identifiers*

Review being conducted of existing prescriptive criteria. Recognition of individual counters / identifiers to be removed unless prescribed by regulations.

### *Crime Scene Services*

New policy (PC 43) was issued Nov 2012 covering the accreditation of crime scene services locations. These are no longer separately accredited providing they are under the control of a NATA accredited testing (examination) site.

### *Medical Testing*

Adoption of ISO 15189:2012. NATA transition policy (PC 45) was published in March 2013. The new Standard will be applied from 1 July 2013. The transition is to be completed by March 2016 as per ILAC / APLAC resolution. A gap analysis worksheet is available for interested facilities. NATA will seek to extend APLAC signatory status to include Medical Testing when next NATA evaluation is due in 2015.

Medical Testing will also be introducing a new surveillance model which will commence as of 1 July 2013. The surveillance model is based on a four year cycle. Further detailed can be obtained by reading Policy Circular 46.

### *Good Laboratory Practice*

An evaluation of NATA's GLP program by the OECD Working Group was conducted in September 2012. The Interim report identified one minor non-conformity.

### *Inspection*

Adoption of ISO/IEC 17020:2012. A NATA transition policy (PC44) was published March 2013 and is applicable from 1 July 2013. ILAC resolution requires that transition be completed by March 2015. A gap analysis worksheet is available. The draft revised ISO/IEC 17020 Application Document is available on NATA website for information purposes only.

### *NATA Approved Signatories*

NATA approved signatories are no longer applicable in any field or program. Approval of individuals (however named) will continue where there are regulatory requirements or third party agreements NATA has entered into.

### *Sleep Services Accreditation*

The joint accreditation program with the Australasian Sleep Association (ASA) was launched in July 2012. ASA Standards for Sleep Disorders Services have been developed which include the principles of ISO 15189. Two accreditations have been granted to date. The surveillance model consists of a four year assessment cycle with a surveillance visit scheduled mid cycle.

## • **Governance Update**

The Rules Review Committee has been asked by the Board to review NATA's current governance structure. A number of recommendations have been made to the Board. A proposal to change the Constitution will be put forward at the 2014 Annual General Meeting.

## • **Report on ILAC Laboratory Committee**

The NATA Members Representative on the ILAC Laboratory Committee (LC) provided a brief update on his attendance at the last ILAC LC meeting. NATA Members were canvassed prior to the meeting regarding what issues they wanted raised at the ILAC LC meeting. Discussions held at the meeting included the following:

The LC discussed the importance of and difficulties associated with proficiency testing (PT) and the need for harmonisation and standardisation of criteria for PT for new technologies. The LC considered this merely requires application of existing principles relating to test validation and clarity in what is PT addressing. In terms of how different accreditation bodies detect poorly performing facilities in a timely manner the LC response was that ISO 17025 allows flexibility in how PT results are used, and therefore harmonisation is not necessarily to be expected.

Discussions were also held on how can a membership in one jurisdiction, who believes outputs of accreditation in another jurisdiction are sub optimal, formally make that known? The mechanics of dealing with concerns about the outputs of an accredited facility in the economy of another Accreditation Body (AB) were discussed and these should initially be lodged with the accredited facility. If necessary, the matter can be taken up by the Regional Body (APLAC for Australia) and ultimately ILAC.