June 2014

Dear Authorised Representative

RE: Update on the Uniform Format for Scopes of Accreditation Project

As you will be aware, there is an ongoing project to ensure the presentation of scopes of accreditation is consistent across Fields and Programs and that individual scopes of accreditation better reflect the actual breadth of testing performed by each facility.

A tabular format has been developed and will be adopted for presentation of scopes. Prior to the approval of the format, stakeholder feedback was gathered at the "proof of concept stage".

Medical Testing facilities traditionally have had "open" scopes, whereby analytes have been added by a facility to their testing suite without necessarily informing NATA. While the open scope philosophy is not envisaged to change, the actual testing for which a facility is claiming accreditation needs to be known and thus recorded by NATA for any given point in time. At present this information is only gathered during an assessment activity.

The project is now at the stage that NATA is gathering data to transcribe current scopes of accreditation into the new format. Accordingly, prior to your next NATA visit, you will find a specifically designed Excel spreadsheet embedded in the Assessment Information Documents (AIDs).

The spreadsheet has combined information which is required to perform assessment activities and information which is required for the tabular scope project. The latter may not be required at the time of the assessment but will need to be captured within the given timeframe detailed below.

<u>The following information within the **test scope tab** is required prior to the assessment:</u>

- **Service (type of test) - Class of test/Scope of Accreditation**
  e.g. General Chemistry, Analytes in general use in cardiac, lipid, liver function, renal function and other profiles and metabolic studies

- **Material / Item / Product**
  e.g. blood, plasma

- **Determination**
  e.g. Alanine transaminase (ALT), alkaline phosphatase (ALP), albumin

- **Technique**
  e.g. Vitros Fusion

- **QAP details (for tests not covered by a QAP alternative arrangement and frequency of program)**
  e.g. RCPA General Serum Chemistry

- **Date Introduced**
  e.g. June 2008

- **Test per month**
  e.g. 2500

- **Commercial or In-House IVD**
  e.g. Commercial

- **For In-house IVD - TGA IVD Framework Classification (i - iv)**
  e.g. N/A

The following within the **test scope tab** may be captured either prior or after the assessment but within **3 months** of the assessment notification date.

- **Procedure**
  e.g. Spectrophotometry

- **Limitations / Range**
  e.g. 20 - 1500 U/L

- **Measurement uncertainty**
  e.g. 5 U/L

All other folders in the embedded spreadsheet are required for completion prior to the assessment.

Some points to note regarding the spreadsheet template are:

- All columns must be populate;
- Columns which are not relevant for a particular test (e.g. the 'MU' column for qualitative tests) will be left blank;

It is recognised this will be a significant impost initially. Hence the additional time granted for all of the information to be submitted.

In conclusion, it is recognised that this is a significant undertaking, however it is an important and necessary one to meet the needs of Members, stakeholders and NATA's obligations.

If you have any further queries in relation to this matter please do not hesitate to contact your Client Coordinator in the first instance.