

9 November 2021

Dear Authorised Representative

The revision of ISO 15189:2012 commenced in 2019. The review of the Standard is a three year project under the responsibility of the ISO TC 212 Committee Working Group 1.

Standards Australia has three representatives on this working group, one being NATA's Sector Manager - Legal & Clinical Services.

The draft standard is now at the DIS (Draft International Standard) stage and we invite your feedback.

The layout of the DIS is different to the current 2012 version of the Standard due to the adoption of the structure consistent with CASCO Resolution 12/2002 (covered in QS-CAS-PROC/01) and the inclusion of the mandatory requirements specified by ISO/CASCO in QS-CAS-PROC/33:

- Resolution 12/2002 covers the layout of CASCO standards in a set order:
 - Terms and definitions
 - Structural requirements
 - Resource requirements (including human resources)
 - Process requirements (including operational functions)
 - Management system requirements
 - Normative annexes
- PROC/33 covers the requirements concerning impartiality, confidentiality, complaints / appeals and management systems.

Should you wish to provide feedback, please complete the template and submit it by email no later than 1 December 2021 to ISO15189DIS@nata.com.au. The relatively short time allowed for providing feedback reflects the period established by ISO, Standards Australia and ILAC.

Your feedback will only be considered if the "Clause / subclause", "Comments" and "Proposed change" columns are completed in the feedback template. Please do not modify the size of the columns and only insert text.

You will notice that certain wording and/or paragraphs in the DIS are highlighted in grey. This text reflects the obligatory language in QS-CAS-PROC/33 that cannot be deleted or changed.

Feedback only received prior to the due date will be considered.

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NATA will consider all feedback received, however, will not provide a response to you. Once all feedback has been reviewed, a consolidated response to Standards Australia and ILAC will be submitted. Note, that it will be Standards Australia (as Australia's ISO member body) and ILAC who will submit comments to ISO/CASCO and not NATA. Accordingly, it will be Standards Australia's and ILAC's decision on which comments will ultimately be submitted. Where opposing feedback is received from NATA Members, NATA will only submit one view in keeping with Standards Australia's and ILAC's processes.

Prior to the adoption of the new standard scheduled to be published in late 2022, NATA will develop a transition policy outlining the process that will apply for accrediting laboratories to the new Standard.

Yours sincerely

Andrew Griffin

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SECTOR MANAGER - LEGAL & CLINICAL SERVICES