

21 April 2006

Standards and Accreditation Study  
Productivity Commission  
PO Box 80  
Belconnen ACT 2606

## **Submission to the Productivity Commission Standards of Accreditation**

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The Royal College of Pathologists of Australasia (RCPA) makes this submission to the above inquiry as an organisation integrally involved in assuring how high quality pathology services are provided in Australian laboratories.

There has been a long established process for setting standards and accreditation of pathology laboratories in Australia for the last 30 years. The process underwent a major external review which was completed in July 2002 (by Corrs Chambers Westgarth), under the auspices the Department of Health and Ageing.

This review recognised that the current standards setting and accreditation arrangements in Australian were of a very high standard, certainly the most sophisticated approach to medical accreditation in Australia. The system was also compared very favourably with the pathology accreditation systems available internationally. It was alluded to, that Australia leads the world in pathology accreditation processes.

There were some recommendations for improvements and the majority of these have been implemented. The Productivity Commission may wish to obtain the full report from the Department of Health and Ageing (DoHA) via;  
[www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pathology-accred-index.htm](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pathology-accred-index.htm)

The existing process is detailed in full in attachment 1 (volume 2, Corrs Chambers Westgarth Report).

In essence, there is a Ministerially appointed body, the National Pathology Accreditation Advisory Council (NPAAC) which sets the standards for pathology laboratories. In doing so the Council uses International Standards such as ISO 15189:2003 (AS4633-2004) and some Australian Standards set by Standards Australia and adapts these for use in the Australian setting.

NPAAC has representation from professional organisations involved in pathology along with State and Territory Government representatives. This allows for practical input into standards from those directly involved in supervising and operating laboratories.

The RCPA considers that the process works well and is much more streamlined than the standard setting done by Standards Australia. The College would not support assigning the setting of standards for pathology laboratories in Australia to Standards Australia.

Further there was a recent review of NPAAC in May 2005 by CaSServ (Conformance and Standards Service Pty Ltd) . The Department of Health's response established an agreed and unanimous position that NPAAC and medical testing were sufficiently different to keep as separate processes. Indeed it was recognised that NPAAC performed a valuable role

separate to that of Standards Australia. Of note, there were only minor recommendations required to bring NPAAC up to international best practice in all its internal procedures.

The Productivity Commission would find the Department of Health and Ageing's response to the review of value.

One area of potential improvement that NPAAC is already considering is the greater use of international standards, and a higher international and publication profile for NPAAC. This will hopefully address concerns re artificial trade barriers.

The separation of the setting of standards by NPAAC from the physical accreditation of laboratories by NATA/RCPA is considered to be a best practice model for ensuring high quality outcomes for testing. As already noted NPAAC uses ISO standards and it is also worth noting that Standards Australia's only contribution to ISO 15189:2003 was the renaming of the standard to AS4633-2004 without any other change to substance or content- this was hardly a helpful change to the profession, and NPAAC has a much better record in this regard.

It is the College's opinion that NATA/RCPA should remain at arms-length as an accrediting body. The huge goodwill generated by a legion of volunteer assessors who are actively involved in delivery of pathology services ensures that laboratories are being reviewed by people who are up to date on the latest technology and quality practices. It also minimises the cost of accreditation dramatically. Any privatisation of the process would result in soaring costs of accreditation.

The relationship between NATA and RCPA is performing accreditation as outlined in the Memorandum of Understanding (attachment 2).

In essence NATA provides the infrastructure and support to provide accreditation while the RCPA provides Fellows to undertake laboratory assessment. Fellows also sit on committees which review accreditation processes, and the College provides policy advice to NATA on a number of issues, for example practical interpretation of standards.

There are occasional concerns expressed from some laboratories, particularly small laboratories that the cost of accreditation is high, however any alternatives that have been considered have always been found to lead to higher costs without any compensatory advantages.

The RCPA would welcome the opportunity to meet with the Commission to discuss the review in more detail.

Yours sincerely

[signed]

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