

# Framework for the Revised TSANZ Respiratory Function Laboratory Standard

## Overview

TSANZ and NATA have partnered together to deliver a joint TSANZ/NATA Respiratory Function Laboratory Accreditation Program.

In preparation for the new program, the current TSANZ Laboratory Accreditation Standard will be transformed into an international framework, using ISO 15189 *Medical Laboratories - Requirements For Quality And Competence* as the basis for this new Standard. This process will retain the technical requirements from the TSANZ Standard whilst introducing management system elements from the ISO Standard.

This body of work is being undertaken by the Respiratory Function Laboratory Accreditation Steering Committee and is expected to be completed in the second half of 2024. NATA will provide more information on the Standard and the specific requirements as these are developed.

To assist facilities in becoming familiar with the new Standard, the Standard headings and sub-headings have been provided below.

## ISO 15189 FRAMEWORK

| General Requirements   | Structural & Governance Requirements   | Resource Requirements  | Process Requirements   | Management System (MS) Requirements   |
|--|--|--|--|---|
| <ul style="list-style-type: none"> <li>• Impartiality</li> <li>• Confidentiality</li> <li>• Requirements regarding patients (safety, wellbeing, rights)</li> </ul> | <ul style="list-style-type: none"> <li>• Legal entity</li> <li>• Laboratory director</li> <li>• Structure &amp; authority</li> <li>• Objectives &amp; policies</li> <li>• Risk management</li> </ul> | <ul style="list-style-type: none"> <li>• Personnel</li> <li>• Facilities &amp; environmental conditions</li> <li>• Equipment</li> <li>• Equipment calibration &amp; MU</li> <li>• Reagents &amp; consumables</li> <li>• Service agreements</li> <li>• Externally provided products &amp; services</li> </ul> | <ul style="list-style-type: none"> <li>• Pre-exam processes</li> <li>• Exam processes</li> <li>• Post-exam processes</li> <li>• Non-conforming work</li> <li>• Control of data &amp; information management</li> <li>• Complaints</li> <li>• Continuity &amp; emergency preparedness planning</li> </ul> | <ul style="list-style-type: none"> <li>• General MS requirements</li> <li>• MS documentation</li> <li>• Control of MS documents</li> <li>• Control of records</li> <li>• Actions to address risks &amp; opportunities for improvement</li> <li>• Improvement</li> <li>• Nonconformities &amp; corrective actions</li> <li>• Evaluations</li> <li>• Management review</li> </ul> |

## NATA Education Courses

If you are looking to get a head start on your knowledge of management systems, NATA's education department runs several courses in quality management systems, including quality, auditing, risk management and laboratory leadership. Our [website](#) has information on the courses and available dates. The courses are available in both face to face and virtual formats.

## Upcoming Events

[TSANZSRS ASM](#) 22-26 March 2024, Gold Coast Convention and Exhibition Centre  
[NATA Accreditation Matters](#) Conference 25-26 June 2024, International Convention Centre Sydney  
TSANZ Education Hub - 10-12 Oct 2024, Melbourne

## Other resources/links

[NATA Newsletter](#). Information about the new joint TSANZ/NATA program and updates on the Standard will be published in the NATA Newsletter. You can sign up free of charge to receive the newsletter [here](#).

Updates will also be provided in the [TSANZ and ANZSRS newsletters](#). These newsletters are issued to TSANZ and ANZSRS members. You can sign up to be a [TSANZ](#) or [ANZSRS](#) member on the respective websites.

The [Australian Council for Clinical Physiologists \(ACCP\)](#), works to recognize appropriate professional standards for clinical physiologists working in Australia. Their [website](#) contains general resources for clinical respiratory physiologists.

## Queries

If you have any queries regarding respiratory function laboratory accreditation, please contact NATA on 1800 666 621, submit a query via our website, or email [tracy.fleming@nata.com.au](mailto:tracy.fleming@nata.com.au)