



Office: Suite 4, Level 1, 760 Pacific Highway, Chatswood, NSW 2067

ABN 17 057 925 836

Respiratory Function Laboratory Accreditation Frequently Asked Questions

Why are TSANZ partnering with NATA to run a joint accreditation program?

The TSANZ-run laboratory accreditation service is no longer financially sustainable and has been loss making for several years. The Board explored several options and decided to partner with NATA after an extensive review of the current Laboratory Accreditation service delivered by TSANZ. This partnership maximises NATA's vast experience in accreditation for testing with the current TSANZ standard to be reviewed and updated in line with the international standard ISO 15189: 2022 medical laboratories - requirements for quality and competence.

Why has TSANZ signed an MoU with NATA?

The TSANZ/NATA Respiratory Function Laboratory Accreditation Program will contribute to better health outcomes and treatment for patients with respiratory and lung health conditions. The Memorandum of Understanding (MoU) formalises the arrangement and sets out the responsibilities of both TSANZ and NATA in jointly administering the Program.

Who is NATA?

NATA is Australia's sole internationally recognised accreditation authority with a long history of accrediting organisations to perform testing activities to national and international standards.

What are the benefits of NATA accreditation?

NATA accreditation uses a proven peer-review model to provide consumers assurance and confidence that the testing done by accredited laboratories for products and services we use every day can be trusted and relied upon.

What is the benefit of the new TSANZ/NATA Respiratory Function Laboratory Accreditation Program?

The existing TSANZ standard will be reviewed and updated in line with the international Standard ISO 15189: 2022 *Medical laboratories - requirements for quality and competence*.

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This will allow laboratories with respiratory, sleep and blood gas services to have one management system covering all three areas, reducing duplication in the implementation and on-going maintenance of the management system.

When will the TSANZ/NATA Respiratory Function Laboratory Accreditation Program come into effect or what is the transition period?

The new TSANZ/NATA Respiratory Function Laboratory Accreditation Program is expected to come into effect by the end of 2024.

Laboratories accredited under the TSANZ process will be recognised as accredited until their current TSANZ accreditation expires, or the end of 2025 (whichever period is greater).

We will provide a more detailed timeline of the transition to the joint program in the coming months.

NATA will be responsible for the "administration of the program". What does that mean?

NATA will manage the day-to-day operations of the TSANZ/NATA Respiratory Function Laboratory Accreditation Program.

How will the new program be established?

The joint TSANZ/NATA Respiratory Function Laboratory Accreditation Program will be established by a Steering Committee whose role will include providing technical advice, reviewing the TSANZ standard and aligning it to ISO 15189:2022, providing guidance on the scope of testing, guidance on development of technical accreditation criteria, strategic advice on industry or emerging issues and technical assessor matters.

Standards

Will the TSANZ Respiratory Function Laboratory Accreditation Program Manual still be used to accredit my facility?

No. The Program manual will no longer be used under the TSANZ/NATA joint program.







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Will the TSANZ Standards for Accreditation (Section 7 of the Program manual) still be used?

The TSANZ Standards will be used in the accreditation process after the revision of the current version.

The standard will be a TSANZ document, and TSANZ will be responsible for maintaining and updating the content.

Why are we adopting the ISO 15189 format and principles?

The adoption of the ISO principles into the TSANZ Standards for Accreditation raises accreditation to an internationally recognised level and covers both managerial and technical requirements.

What will be the biggest changes in the Standard?

The work revising the TSANZ Standard is just beginning. Changes to the existing requirements will largely be editorial, unless the steering committee identifies a requirement that needs to be updated.

The introduction of the management system elements from ISO 15189 will be a new requirement that respiratory labs will need to become familiar with. The management system in ISO 15189 provides a structured framework on which to base your governance system.

My lab is already accredited, when will we need to adopt the revised Standard for the new accreditation program?

You will need to adopt the new Standard prior to seeking accreditation under the joint TSANZ/NATA program.

A document identifying the changes between the current TSANZ Standards for Accreditation, and the revised standard will be produced in due course to assist you in identifying any gaps.

Accreditation Process

What is NATA's assessment process?

NATA assessments are first and foremost a peer review process. NATA relies heavily on the specialist knowledge and experience of its volunteer technical assessors.

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How does it differ from the TSANZ process?

The assessment process undertaken by TSANZ and NATA are similar. Both require a submission of policies and procedures prior to the visit. Both include an on-site assessment with peer assessors. Both require the facility to respond to any issues identified before accreditation can be granted.

Whilst the details of the NATA process have yet to be finalised, the facility being assessed should only experience minor differences in the process.

Will the TSANZ accreditation process continue?

TSANZ will finish assessing applications for accreditation that are at the site visit phase. No new applications for accreditation will be accepted. Once the applications in progress are completed, the TSANZ Accreditation program will be discontinued.

TSANZ will communicate directly with the affected facilities and provide greater detail specific to each facility's circumstances.

When do I need to transition to the joint TSANZ/NATA accreditation program?

Accredited facilities are expected to transition to the joint TSANZ/NATA accreditation program once it commences, and prior to their current TSANZ accreditation expiring.

What happens if my TSANZ accreditation expires?

All sites that expire before 2025 will be granted an extension until December 2025. If your TSANZ accreditation expires after this period, you will no longer be recognized as an accredited facility.

Once the TSANZ/NATA program becomes operational, you can apply for accreditation at any time.

Technical knowledge/expertise

What does NATA know about respiratory function laboratories?

NATA's core business is accreditation. As NATA assessments are a peer review process, NATA relies heavily on the specialised knowledge and experience of its volunteer technical assessors.





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How will NATA ensure that the standards that have been set are maintained?

NATA is committed to ensuring that the standards that have been set are maintained. This will be achieved by:

- using the revised TSANZ Standards for Accreditation as the criteria against which facilities are assessed
- ensuring that the technical rigour of the assessment is maintained through the inclusion of appropriate volunteer technical assessors.

LAQC

Will the LAQC still exist under the TSANZ/NATA program?

The LAQC will continue whilst accreditations are being finalised under the TSANZ program. Once these assessments have been completed, the LAQC will be disbanded.

Assessors

I am an assessor under the current TSANZ process. What happens to me?

TSANZ will be contacting each of its assessors to seek permission to pass on their details to NATA. NATA will then contact you and invite you to continue as a volunteer assessor under the joint TSANZ/NATA program.

I am currently involved on a panel. Should I continue to progress the work on this accreditation?

Each panel member will receive a notification from TSANZ in the coming days. You will be advised whether or not to proceed with the assessment/s in which you are involved.

I am not an assessor under the current TSANZ process but am interested in becoming an assessor under the joint TSANZ/NATA program. Where do I find out more information?

You can visit the NATA website to obtain information on becoming an assessor. As the development of the program progresses, NATA will seek expressions of interest from TSANZ and ANZSRS members who wish to become an assessor. More details will be released in due course.

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What is involved in being an assessor with NATA?

NATA assessors are volunteers who are selected on the basis of their technical knowledge, expertise, and familiarity with relevant professional issues.

Fees

Will the accreditation fees be changing?

All facilities that apply for accreditation under the TSANZ/NATA joint program will be charged in accordance with the NATA fee schedule.

How much will TSANZ/NATA accreditation cost?

The TSANZ/NATA joint program fee schedule will be released in due course. Cost estimates can be provided by NATA upon request and can assist with preparing budgets for your department.

More information

Where can I find more information about the changes?

Changes to the accreditation can be found on the Website, newsletter and/or socials.

How will I know about upcoming changes?

- The changes to the accreditation program will be communicated directly to accredited/applicant labs, and TSANZ members via email and newsletters.
- Changes will also be communicated via the NATA newsletter, and both the TSANZ & NATA social media channels -

Can I subscribe to the TSANZ newsletter if I'm not a TSANZ member?

No, the TSANZ newsletter is only available to TSANZ members.







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I am a TSANZ member, but I don't currently receive the newsletter. How can I check/update my details?

As a TSANZ member, you have access to TSANZ regular communications, the TSANZ e-news, Policy and Advocacy update and Research Roundup. Communications are sent to your email that you registered with your membership. If you would like to check or update your email for receiving TSANZ communications, please email the Membership Officer at TSANZOffice@thoracic.org.au.

Can I subscribe to the NATA newsletter?

Yes - you don't need to be part of an accredited facility to subscribe to the NATA newsletter. Sign up <u>here</u>.

What education resources/guidance documents will be available for the TSANZ/NATA accreditation program and the revised Standard?

A series of resources and guidance documents will be released as the program is developed. Advice regarding new publications will be communicated through both the TSANZ and NATA communication channels.

Is my TSANZ membership impacted by the accreditation program changing?

No, your TSANZ membership will remain unchanged.

I still have questions. Who do I contact?

Questions regarding accreditation under TSANZ should be directed to TSANZ.

TSANZ

TSANZ Accreditation - Labaccreditation@thoracic.org.au

Questions regarding the accreditation process under the joint TSANZ/NATA program, or the revised Standard should be directed to NATA.







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NATA

Tracy Fleming, Deputy Sector Manager, Imaging Tracy.fleming@nata.com.au 1800 621 666 (free call)

