



RESPIRATORY LABORATORY ACCREDITATION PROCESS KEY TASKS AND INDICATIVE TIMELINES

Exert from Program Manual, July 2021, Section 3.1, Overview of the accreditation process.

TSANZ aims to have an accreditation finished within 9 months and to keep the extra work burden to a minimum for the laboratory staff. The broad 9 month time-frame for the accreditation process and a summary of the key steps and tasks is described in Table 1 below.

Delays and extensions to these indicative time frames do occur. Delays may be due to unavailability of Assessors or Laboratory Staff at critical times. Timeframes may need to be extended if the Laboratory needs time to respond to panel queries or to implement changes in their documentation or practices, required in order to meet the Standards.

Steps in the process	Tasks	Who	Required time frames
	<ul style="list-style-type: none"> Laboratory prepares application and submits to the TSANZ Office 	Laboratory	
1. Administrative checks and appointment of assessor panel	<ul style="list-style-type: none"> On receipt, the application will be reviewed to ensure all required documents have been submitted (incomplete applications will not be sent for review) Invoice raised for the application fee The assessor panel (consisting of three laboratory accreditation assessors) will be appointed by the LAQC 	TSANZ Office LAQC	4-6 weeks
2. Panel initial evaluation and initial evaluation report	<ul style="list-style-type: none"> Assess laboratory manual contents against accreditation standards; complete Initial Evaluation template TSANZ Office arranges teleconference with panel and LAQC member to discuss evaluation Assessor panel Chair to consolidate panel evaluation into a report for the laboratory and forward the report to the TSANZ Office TSANZ Office/LAQC Chair reviews the initial evaluation report and releases to the laboratory with a cover letter 	Assessor panel Assessor panel Chair TSANZ Office/ LAQC Chair	6 weeks 2 weeks 1 week
3. Laboratory response to the initial evaluation report	<ul style="list-style-type: none"> Laboratory provided with the panel's initial evaluation report Laboratory prepares response and sends to the TSANZ Office 	Laboratory	4 weeks

Steps in the process	Tasks	Who	Required time frames
4. Panel review laboratory's response	<ul style="list-style-type: none"> Laboratory's response forwarded to the assessor panel Panel reviews the response and decides whether to proceed to the site visit If site visit is not recommended, further feedback will be provided to the laboratory for their action 	TSANZ Office	1 week
		Assessor panel	2 weeks
5. Site visit	<ul style="list-style-type: none"> Date of the site visit is arranged at a mutually convenient time for the panel members and laboratory Invoice raised for the site visit fee TSANZ Office liaises with the panel Chair and the laboratory to determine a suitable timetable for the day Site visit is conducted 	TSANZ Office / Assessor Panel / Lab	1-2 months
		Assessor panel / laboratory	1-3 days
6. Final report and recommendations	<ul style="list-style-type: none"> In consultation with other panel members, the panel Chair prepares final report and recommendations and forwards to the TSANZ Office TSANZ Office / LAQC Chair review the final report in order to secure LAQC endorsement. A teleconference between the assessor panel and the LAQC member involved in the review of the initial evaluation report is required to discuss mandatory recommendations and how compliance will be assessed. If accreditation is not recommended, step 7 is commenced. The final report may be referred to the Board for review if recommended by the LAQC. If accreditation of the laboratory is recommended, the final report is endorsed by the LAQC and step 9 is commenced. 	Assessor panel / Chair	1 week
		TSANZ Office / LAQC Chair	2 weeks
		Chair / Board	(Will take additional time)
7. Accreditation not initially recommended	<ul style="list-style-type: none"> If accreditation has not been recommended, the laboratory will be provided with the final report listing the mandatory requirements that must be addressed in order to meet the requirements for accreditation, and a time frame for action. The laboratory is provided 3 months to address the mandatory requirements. The laboratory is to provide a written response to the TSANZ Office including appropriate evidence of how the mandatory requirements have been met. 	TSANZ Office	1 week
		Laboratory	3 months (may be adjusted by the LAQC dependent on circumstances)

Steps in the process	Tasks	Who	Required time frames
8. Further review of laboratory response to mandatory recommendations	<ul style="list-style-type: none"> The TSANZ Office receives the laboratory response addressing the mandatory requirements and distributes to panel and LAQC 	TSANZ Office	1 week
	<ul style="list-style-type: none"> The laboratory response is reviewed by panel and LAQC and assessed as to whether the mandatory recommendations have been met and whether accreditation can now be recommended 	Panel / LAQC	2 weeks
	<ul style="list-style-type: none"> If accreditation is not recommended, communication is sent to the laboratory from the LAQC in the form of a proforma report clarifying the mandatory recommendations that must be addressed in order to meet the requirements for accreditation, and a time frame for action. Cycle through steps 7 and 8 at the discretion of the LAQC, subject to satisfactory progress. 	LAQC	1 week
	<ul style="list-style-type: none"> If accreditation is recommended, a supplementary panel report is prepared, and then steps 6 and 9 are followed. 	Panel	1 week
9. Accreditation recommended	<ul style="list-style-type: none"> When accreditation is recommended by the assessor panel and documented in a final or supplementary report, accreditation is confirmed via LAQC endorsement of the panel's report, the TSANZ Office issues the report, confirmatory letter and a certificate of accreditation to the laboratory. Accreditation will be recommended for a period of five (5) years from the date of the site visit for first time accreditations and from the date of expiry for re-accreditations, subject to successful interim assessment. 	TSANZ Office	1 week
9a. Successful accreditation	<ul style="list-style-type: none"> Successful accreditation requires a commitment to an interim quality assurance desktop assessment process. The results of this assessment may trigger a further site visit and failure to deliver may result in a lapse in accreditation. 		

