Understanding the New TSANZ Respiratory Function Laboratory Accreditation Standard

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Speaker Disclosure

- The presenter has advised that the following presentation will NOT include discussion on any commercial products or service and that there are NO financial interests or relationships with any of the Commercial Supporters of the Education Hub.

- Thank you to TSANZ for providing a Travel Grant to this event

Outline

- Overview of ISO standard 15189
- How to interpret a standard
- Key changes and similarities (Old vs New)
- Summary

What is an ISO Standard?

ISO standards are internationally agreed by experts

Think of them as a formula that describes the best way of doing something.

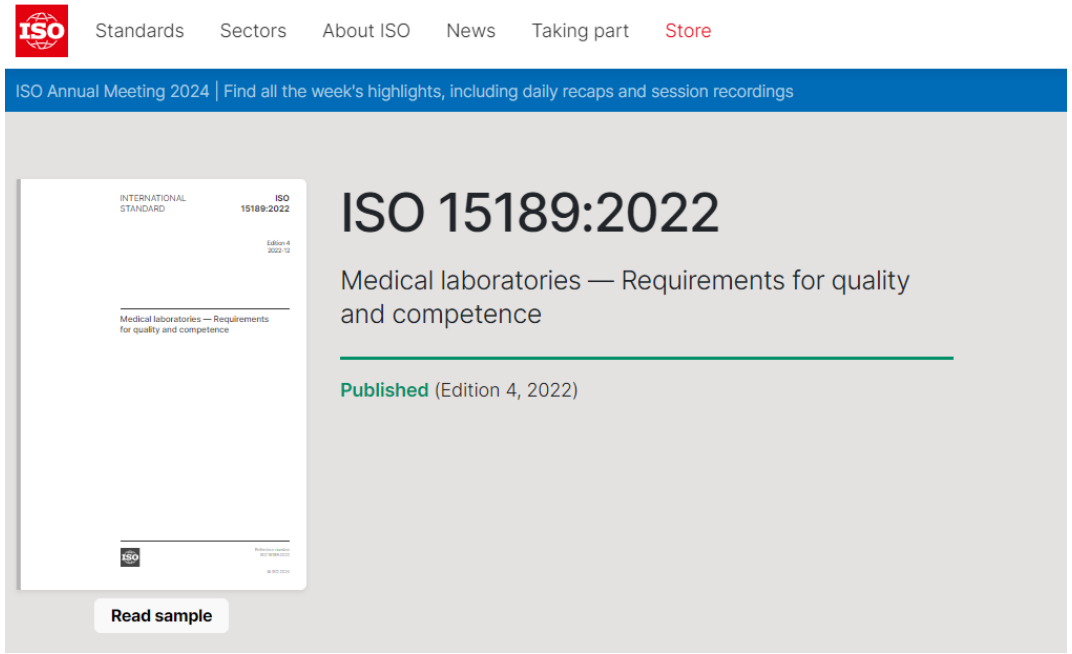
It could be about making a product, managing a process, delivering a service or supplying materials – standards cover a huge range of activities.

Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators.

https://www.iso.org/standards.html

- The International Organization for Standardization (ISO) was founded in 1947 and is headquartered in Geneva, Switzerland.

ISO Standard 15189



- The new TSANZ/NATA standard is based on ISO standard 15189
- Pathology and Sleep laboratories accreditation is based on this standard

Role of the Steering Committee

- The role of the Steering Committee is to provide technical advice to NATA.

This includes:

- Developing the accreditation program
- Revising the Standards
- Defining the testing activities (scope of accreditation)
- Providing advice on technical issues
- Approving technical assessors

Steering Committee Members

- Dr Sonya Johnston
- Mr Brendan Kennedy
- Ms Brigitte Borg
- Mr Danny Brazzale
- Ms Lauren Bussell
- A/Prof Leanne Gauld
- Dr Christopher Htun
- Dr John McLachlan
- Prof Hiran Selvadurai

- Group of Respiratory Physicians and Scientists

Thank you to Tracy Fleming (NATA)

Interpreting a Standard

- “Must” and “shall” describe mandatory requirements.
- “Should” and “may” are related to recommendations

Old (2021) vs New (2024) standard

- Provide an overview of the main changes to the new standard
- Some of the requirements in the new standard may not have an equivalent in the old standard, so some new concepts will be introduced.
- Not possible to cover all the changes
- The standards are not final yet, some wording (but not principle or intent) may change

Don’t Panic

- The TSANZ standard translated well to ISO 15189
- The language and terms are different

Governance - New Standards

- Expanded in the new standards.

- Includes requirements for,
  - Impartiality
  - Risk Management

Impartiality

- Impartiality is not being biased in one direction or another.

TSANZ 2021	TSANZ 2024
- **Impartial, Impartiality** is not mentioned in the TSANZ 2021 standards	4.1 Impartiality a) Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard **impartiality**. b) The laboratory management shall be committed to **impartiality**. c) The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise **impartiality**. **Impartiality** is mentioned multiple times.

Risk Management

TSANZ 2021	TSANZ 2024
Risk Management is not mentioned in the TSANZ 2021 standards	5.6.1 Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its tests and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).

How to approach these new Governance requirements?

- Hospitals will have policies you can refer to

Impartiality • **Equipment Procurement** • **Code of Conduct** • **Sponsorships** • **Conflict of Interest**	**https://webapps.schn.health.nsw.gov.au/epolicy/policy/5422** **NSW Health Code of Conduct** **Sponsorships Policy - NSW Health** **https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2015_045.pdf**
Risk Management	https://webapps.schn.health.nsw.gov.au/epolicy/policy/4390

What is a Nonconformity?

- A nonconformity is the nonfulfillment of a requirement.

- This can encompass various issues, such as departures from established procedures, failure to meet customer expectations, or noncompliance with regulatory requirements.

Nonconformities

TSANZ 2021

7.2.6 Quality assurance program

Additionally laboratories should also incorporate the following activities into their quality assurance program:

- **identification and control of nonconformities;**
- **corrective actions;**
- **preventive actions;**
- **internal audits, with resulting actions and changes; and**
- **management review.**

TSANZ 2024

7.7 Non Conforming Work

The laboratory shall have a process for when any aspect of its laboratory activities or test results do not conform to its own procedures, quality specifications, or the user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria).

Nonconformities – New Standard

8.7 Nonconformities and corrective action

When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:

- take immediate action to control and correct the nonconformity;
- address the consequences, with a particular focus on patient safety including escalation to the appropriate person;

b) determine the cause(s) of the nonconformity;

Nonconformities – New Standard

c) evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by:

- reviewing and analysing the nonconformity;
- determining whether similar nonconformities exist, or could potentially occur;
- assessing the potential risk(s) and effect(s) if the nonconformity recurs;

d) implement any action needed;

Nonconformities – New Standard

e) review and evaluate the effectiveness of any corrective action taken;

f) update risks and opportunities for improvement, as needed;

g) make changes to the management system, if necessary

Corrective Action Request, Root Cause Analysis

- Corrective Action Request (CAR) – change request that documents an issue with a process or product.
  - helps to document, create, implement, and verify the actions taken.

- Root Cause Analysis (RCA) is the process of discovering the root causes of problems
  - helps trace recurring problems to their source

Documentation of Nonconformities

DATE	INCIDENT NO./CAR#	ISSUE	SARA No if Applicable	CLASSIFICATION	ASSIGNED TO	ACTIONS TAKEN/RESOLUTION	STATUS	RELATED TO
1/07/2024	1	DLNO, Fixed setting for PA02 issue, measured DMCO and vc - not aligning to Zarvosky		Major	Hugh Fitzgerald, Brendan Kennedy	CAR, RCA	CLOSE	EQUIPMENT
1/07/2024	2	Treadmill engaging emergency stop without prompt during use		Major	Hugh Fitzgerald, Brendan Kennedy	CAR, RCA	CLOSE	EQUIPMENT
1/07/2024	3	DLCO - Vyaire, Gas cylinder leak. Body Box in Room 82RF005		Major	Beth Weldon, Brendan Kennedy	CAR, RCA	CLOSE	EQUIPMENT
8/07/2024	4	DLCO - Medisoft DLCO reads above specified limit with Syringe		Minor	Hugh Fitzgerald, Brendan Kennedy	CAR	ACTIVE	EQUIPMENT
8/07/2024	5	RFU request list was not read on Friday, inpatient was not tested		Minor	Brendan Kennedy	CAR, RCA	CLOSE	PERSONNEL
8/07/2024	6	DLCO - IVC Body Box in Room 82RF005 > 75ml tolerance		Minor	Merilyn John, Brendan Kennedy	CAR	ACTIVE	EQUIPMENT
8/07/2024	7	Processing Capnostat and DSR		Minor	Brendan Kennedy	CAR	CLOSE	PERSONNEL
10/07/2024	8	Wrong weight entered in patient file for previous visit by CW		Minor	Merilyn John	CAR	CLOSE	PERSONNEL
11/07/2024	9	Patient tested on wrong MRN (file)	RITM3640080	Minor	Brendan Kennedy	CAR	CLOSE	PERSONNEL
12/07/2024	10	Patient tested on wrong MRN (file)	RITM3642608	Minor	Brendan Kennedy	CAR	CLOSE	PERSONNEL
25/07/2024	11	Patient tested on wrong MRN (file), after incorrect patient triage/check in	RITM3671087	Minor	Hugh Fitzgerald	CAR, RCA	CLOSE	PERSONNEL
29/07/2024	12	My message - EMR interface, not sending reminders	INC2651587	Minor	Julie-Ann Thompson, Brendan Kennedy	CAR	CLOSE	EQUIPMENT
30/07/2024	13	Upgrade to Sentrysuite 3.30.2		Major	Brendan Kennedy	CAR, RCA	ACTIVE	EQUIPMENT
30/07/2024	14	Data cube link not working after SES upgrade to 3.30	RITM3682394	Minor	Brendan Kennedy	CAR	CLOSE	EQUIPMENT
1/08/2024	15	Wrong report sent to EMR	RITM3688298	Minor	Beth Weldon	CAR	ACTIVE	PERSONNEL
26/08/2024	16	Incorrect patient ethnicity listed on a patient result		Minor	Hugh Fitzgerald	CAR	CLOSE	PERSONNEL
6/09/2024	17	DLCO - Vyaire, Gas cylinder leak. Body Box in Room 82RF007		Minor	Brendan Kennedy	CAR	ACTIVE	EQUIPMENT

- May or may not change your process
- Does change time required for Documentation

Corrective Action Request (CAR)

the children's hospital at Westmead

The Sydney children's Hospitals Network

CORRECTIVE ACTION REQUEST

Respiratory Function Unit
The Children's Hospital Westmead
Author: Brendan Kennedy, Version 1. 01/07/2024
Location: G:\RESPIR\Data\brendan.kennedy1\RFU Forms\QA\Quality Management Items\RFU)

CAR# 2

CAR issued to: Hugh Fitzgerald

Plan for action required by: Hugh Fitzgerald, Brendan Kennedy

Source of request:

Internal audit	☐
External audit	☐
Patient staff complaint	☐
Management review	☐
Internal observation	☒
Inspection	☐
Data analysis and review	☐
Other	☒

CORRECTIVE ACTION REQUESTOR TO FILL IN THE BELOW SECTION ONLY

Describe the non-conformity. Attach any relevant records or documents. What is the non-conformity and the evidence?

Hardware - Treadmill engages emergency stop during testing without prompts from patients or staff. Hardware error, requiring action.

Actions required:

1. Cease exercise testing on the treadmill until resolution (repair or replacement).
2. Hugh and Brendan engage vendors for technical help and quotes for a new treadmill (Vyaire, Medisoft etc.)
3. Email sent to Hiran Selvadurai (Head o Respiratory Medicine at CHW) outlining the issue, and our concerns moving forward regarding the safety of exercise testing.
4. Membrane for the treadmill has been replaced in the interim.
5. Discussions have taken place with Respiratory Head of Department (Hiran Selvadurai) and clinical program chair (Kirsten Adnum).
6. We are awaiting funding for a new treadmill, it has been placed on the equipment list.

the children's hospital at Westmead

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CORRECTIVE ACTION REQUEST

Respiratory Function Unit
The Children's Hospital Westmead
Author: Brendan Kennedy, Version 1. 01/07/2024
Location: G:\RESPIR\Data\brendan.kennedy1\RFU Forms\QA\Quality Management Items\RFU)

7. Treadmill membrane has been investigated and 'repaired' by company technician.
8. The same issue occurred (31/7/24) despite the 'exploratory' service, which was not a sure fix for the issue raised (emergency stop auto engages during testing). All exercise testing will be ceased until a new treadmill is purchased.
9. New treadmill ordered

Completion date:

08-08-24

Comments:

Staff member's name: Hugh Fitzgerald
Date: 01/07/24

Root Cause Analysis (RCA)

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The Sydney children's Hospitals Network

ROOT CAUSE ANALYSIS

Respiratory Function Unit
The Children's Hospital Westmead
Author: Brendan Kennedy, Version 1. 01/07/2024
Location: G:\RESPIR\Data\brendan.kennedy1\RFU Forms\QA\Quality Management Items\RFU)

CAR# 2

Issue: Hardware – Treadmill Emergency Stop Malfunction

Medical significance (0-10) [0= no impact 10= critical]	10
Impact on service (0-10) [0= no impact 10= catastrophic]	10

Does the referring physician need to be informed? Yes

Does this issue need to be raised as an incident to the Local Health Network? No

	Yes	No
Were there issues related to patient assessment in this event?	☒	☐
Were issues related to staff training or staff competency a factor in this event?	☐	☒
Was equipment (or the use or lack of use of equipment) involved in this event in any way?	☒	☐
Was a lack of information or misinterpretation of information a factor in this event?	☐	☒
Was communication a factor in this event?	☐	☒
Were appropriate policies/procedures or guidelines – or lack thereof- a factor in this event?	☐	☒
Was a failure of a safety mechanism or a barrier, designed to protect the patient, staff, equipment, or environment a factor in this event?	☒	☐
Were specific patient issues a factor in this event?	☐	☒

Root cause(s) identified. Describe root cause.

Hardware - Treadmill engages emergency stop during testing without prompts from patients or staff. Hardware error, requiring action.

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ROOT CAUSE ANALYSIS

Respiratory Function Unit
The Children's Hospital Westmead
Author: Brendan Kennedy, Version 1. 01/07/2024
Location: G:\RESPIR\Data\brendan.kennedy1\RFU Forms\QA\Quality Management Items\RFU)

Recommendation:

Corrective action	☒
Preventive action	☐
No action	☐

Action Description:

Refer to CAR# 2

Staff member's name:

Hugh Fitzgerald

Assigned to:

Hugh Fitzgerald, Brendan Kennedy

Manager's comments:
No error from staff. Hardware issue.

Audits, Test Numbers

TSANZ 2021

7.2.1.3 Workload and resources

- A regular updated audit of the laboratory's workload in terms of number of tests of each particular type must be kept and these records must be available on a quarterly or yearly basis

TSANZ 2024

5.5.4 Objectives and policies

The laboratory shall establish quality indicators (QI) to evaluate performance throughout key aspects of pre-test, test (including) and post-test processes and monitor performance in relation to objectives.

Note: QI's must include, as a minimum, the following:

- number of tests of each particular type
- workload audits

Referrals – Risk Stratification

TSANZ 2021

7.2.3 Patient referral, appointments, handling, documentation

- The laboratory must demonstrate systems to cope with the demands for its services. Where demand exceeds capacity, the laboratory must have a system for prioritising cases perceived to be urgent. The laboratory should be able to assess new patients within two (2) weeks of referral (where appropriate). Urgent cases must be assessed within two (2) working days.

TSANZ 2024

5.5.4 Objectives and policies

- waiting periods for routine and urgent studies in line with clinical risk stratification;

Referrals – Further Information

7.3.3 Procedures must exist for:

- prompt, efficient handling of patient referrals,
- the laboratory's criteria for acceptance
- communication with the referring doctor, where necessary.
- Triaging of referrals, including timeframes for triaging categories, definition of priority categories and timeframes for testing to be performed. (see 5.5.4)

Reporting – Turn around time

TSANZ 2021	TSANZ 2024
7.2.3 Patient referral, appointments, handling, documentation	7.6 Post-test processes
• Reports and correspondence must be completed promptly (within five (5) working days) following each patient contact	• 7.6.1.2 Reports and correspondence must be completed within five (5) working days following each patient contact.

Reporting Turn Around Times

- NOTE: reporting turnaround times (TAT) must be reported in absolute time. Use of average or median values are not acceptable.

- Where the TAT are non-conforming (i.e. above 5 working days), the laboratory must implement strategies to reduce these timeframes.

	Reports	%
More than 5 Business Days	50	13.23
Less than 5 Business Days	328	86.77
Total	378	100.00

Reporting Turn Around Times

REPORT_STATUS	TEST_Date	Test Time	REPORT_FINAL_DT_TM	Report Time	DAYS_TO_FINAL_REPORT	Business Days
Final	2/07/2024	3:04:00 AM	5/07/2024	9:18:00 AM	2.7	3.00
Final	2/07/2024	2:50:00 AM	5/07/2024	9:19:00 AM	2.7	3.00
Final	2/07/2024	1:20:00 AM	5/07/2024	9:20:00 AM	2.8	3.00
Final	2/07/2024	1:52:00 AM	5/07/2024	9:19:00 AM	2.8	3.00
Final	2/07/2024	2:23:00 AM	5/07/2024	9:19:00 AM	2.7	3.00
Final	2/07/2024	2:39:00 AM	5/07/2024	9:19:00 AM	2.7	3.00
Final	2/07/2024	1:28:00 AM	5/07/2024	9:19:00 AM	2.8	3.00
Final	3/07/2024	8:14:00 AM	5/07/2024	9:17:00 AM	2.0	2.00
Final	3/07/2024	1:58:00 AM	5/07/2024	9:11:00 AM	1.	2.00
Final	3/07/2024	11:58:00 AM	5/07/2024	9:15:00 AM	1.8	2.00
Final	3/07/2024	10:02:00 AM	5/07/2024	9:17:00 AM	1.9	2.00
Final	3/07/2024	10:10:00 AM	5/07/2024	10:00:00 AM	1.9	2.00
Final	3/07/2024	3:07:00 AM	5/07/2024	9:10:00 AM	1.7	2.00
Final	3/07/2024	12:18:00 PM	5/07/2024	9:14:00 AM	1.8	2.00
Final	3/07/2024	9:28:00 AM	5/07/2024	9:17:00 AM	1.9	2.00
Final	3/07/2024	3:40:00 AM	5/07/2024	9:09:00 AM	1.7	2.00
Final	3/07/2024	3:42:00 AM	5/07/2024	9:07:00 AM	1.7	2.00
Final	3/07/2024	5:01:00 AM	5/07/2024	9:07:00 AM	1.6	2.00
Final	3/07/2024	10:44:00 AM	5/07/2024	9:16:00 AM	1.9	2.00
Final	3/07/2024	8:12:00 AM	5/07/2024	9:18:00 AM	2.0	2.00
Final	3/07/2024	7:42:00 AM	5/07/2024	9:18:00 AM	2.0	2.00
Final	3/07/2024	2:43:00 AM	5/07/2024	9:10:00 AM	1.7	2.00
Final	3/07/2024	8:27:00 AM	13/07/2024	9:33:00 PM	10.5	7.00
Final	3/07/2024	8:32:00 AM	5/07/2024	9:17:00 AM	2.0	2.00
Final	3/07/2024	12:37:00 PM	5/07/2024	9:14:00 AM	1.8	2.00
Final	3/07/2024	10:53:00 AM	5/07/2024	9:16:00 AM	1.9	2.00
Final	3/07/2024	11:37:00 AM	5/07/2024	9:15:00 AM	1.	2.00
Final	3/07/2024	8:46:00 AM	5/07/2024	9:17:00 AM	2.0	2.00
Final	3/07/2024	11:24:00 AM	5/07/2024	9:16:00 AM	1.9	2.00
Final	3/07/2024	1:16:00 AM	5/07/2024	9:49:00 AM	1.8	2.00
Final	3/07/2024	10:21:00 AM	5/07/2024	9:16:00 AM	1.9	2.00
Final	3/07/2024	11:32:00 AM	5/07/2024	9:15:00 AM	1.9	2.00
Final	4/07/2024	2:05:00 AM	5/07/2024	9:02:00 AM	0.7	1.00

Information Systems Management (TSANZ 2021)

TSANZ 2021

7.2.4.1 Laboratory test data

- Test data and records, including data and records maintained remotely from the site of the test, must have built in safeguards including, but not limited to, data and document backup, and control procedures.

- In the case of traditional processes of recording, calculation and typing, printed pro-forma test documents should be used to ensure consistent recording of critical information.

- It is the responsibility of the signatory to ensure that all calculations and data transfers have been checked before the report is authorised.

Information Systems Management (TSANZ 2024)

7.8.2.1 Information systems management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of test data and information shall be:

a) validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modifications to commercial off-the shelf software, shall be authorized, documented and validated before implementation;

NOTE 1 Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as laboratory equipment, hospital patient administration systems and systems in primary care.

Information Systems Management

NOTE 2

Commercial off-the-shelf software used within its designed application range can be considered sufficiently validated (e.g. word processing and spreadsheet software, and quality management software programs).

a) documented, and the documentation readily available to authorized users, including that for day to day functioning of the system;

b) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguarded data against tampering or loss;

Information Systems Management

c) operated in an environment that complies with supplier specifications or, in the case of noncomputerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions; and

e) calculations and data transfers shall be checked in an appropriate and systematic manner.

Information Systems Management

7.8.5 Downtime Plans

- **The laboratory shall have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities.**
  - **This might include systems that will work locally in the case of a server or hospital wide failure**
  - **It may just mean that you document that under certain conditions the laboratory may need to close**

Identification

TSANZ 2021	TSANZ 2024
• 7.2.8.3 Identification The laboratory must be clearly identified by ~~signage~~ or appropriate wayfinding, telephone, and stationery so that it can be easily found and/or accessed.	6.3.1.4 The laboratory must be clearly identified by appropriate wayfinding, telephone, and stationery so that it can be easily found and/or accessed.

NEW TSANZ 2024- Requirements regarding patients

TSANZ 2024

4.3.1

Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement the following processes:

b) provision of patients and users with publicly available information about the test process, including costs when applicable, and when to expect results;

New TSANZ 2024 Equipment Labels

- Each item of equipment that can significantly influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained.

- Note: examples of uniquely labelled can include asset number, serial number, permanently affixed ID label, but does not include printers, scanners etc.

TSANZ 2024 - Reagents and Consumables

6.6.9 Records shall be maintained for each critical reagent and consumable that contributes to the performance of tests. These records shall include, but not be limited, to the following:

a) identity of the reagent or consumable;

b) manufacturer's information, including instructions, name and batch code or lot number;

c) date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service;

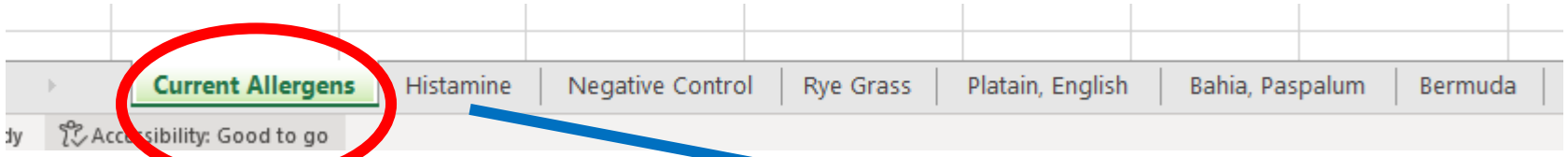
d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use.

Note 1: Criticality of reagents and consumables is determined based on risk

Note 2: Examples of critical reagents and consumables may include allergens and gases

Reagents and Consumables

- Example Allergens



Histamine (HS7099ED)

Serial Number	LOT Number	Bottle Size	Commission Date	Expiry Date	Decomission Date
5000000064	E2300104	5 mL	3/10/2024	27/02/2026	-

Current Allergens

Allergen	Item Number	Serial Number	LOT Number	Bottle Size	Commission Date	Expiry Date
Histamine	HS7099ED	5000000064	E2300104	5 mL	3/10/2024	27/02/2026
Negative Control	GNCS	5599530	428085	5 mL	6/08/2024	6/02/2027
Rye Grass	T24	5513018	426837	5 mL	11/09/2024	8/07/2026
Plantain, English	54	5276869	423093	5 mL	21/09/2024	15/11/2026
Bahia, Paspalum	231	5475975	426266	5 mL	12/09/2024	15/11/2026
Bermuda	T2-A	213051	Sp03182201-05	5 mL	1/10/2024	18/03/2026
Cat hair	TE3	5210895	421857	5 mL	19/08/2024	23/07/2025
Dog Hair	E7	5394043	424827	5 mL	2/10/2024	15/11/2026
HDM (Pteronys)	B70 / GB70A02	3010509	415010	5 mL	3/10/2024	6/08/2025
HDM (Farinae)	B64	5122572	419982	5 mL	11/09/2024	3/09/2025
Alternaria	M1-A	5224874	422573	5 mL	6/08/2024	15/11/2026
Aspergillus	M3	-	A20C014P	2.5 mL	6/08/2024	1/10/2025

External Quality Control – TSANZ 2021

- 7.3.2.3 External quality control (old)

- ~~External quality control, that is participation in inter-hospital proficiency testing programs, assists in monitoring the effectiveness of internal quality control procedures.~~

TSANZ 2024 – Procedures (External Providers)

6.8.3 The laboratory shall have procedures and retain records for:

a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;

b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;

d) taking any actions arising from evaluations of the performance of the external providers.

Examples, IT (version of windows), interface with existing equipment, cost, warranty, lifespan, operating costs.

New TSANZ Critical result reports

7.6.2 Critical result reports

When test results fall within critical decision limits established by the laboratory:

a) the referrer or other authorized person is notified as soon as relevant, based on clinical information available;

b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;

c) the laboratory shall have an escalation procedure for laboratory personnel when a referrer or other responsible person cannot be contacted.

Critical Results Examples

- FEV1 ≤ -4 z-scores on first visit
- A fall in FEV1 greater than 30% predicted from a previous visit
- Spirometry induced bronchospasm

Summary

- New Governance requirements
- Nonconformities
- Waiting times based on risk stratification
- Information System management

Summary

- Requirements regarding patients
- Equipment Labels
- Reagents and Consumables
- External providers
- Critical result reports