



# ISO 15189:2022 Implementation Checklist

## **Instructions**

This checklist identifies the clauses of ISO 15189:2022 where there are new or major changes to requirements compared to the previous 2012 version of the Standard. The checklist does not include the clauses where new or major changes are already covered by existing *NPAAC Requirements*.

Minor changes also have not been included in this checklist.

Details of all changes (minor, major and new) to requirements in the new version of the Standard, compared to the previous version, are documented in the *Gap Analysis* available from the NATA website at [www.nata.com.au](http://www.nata.com.au).

Prior to an accredited facility's scope of accreditation being updated to the new version of the Standard, a response together with supporting evidence to the clauses identified in this checklist must be provided. Confirmation of compliance with all relevant changes will occur during the on-site NATA assessment.

For a multi-site facility (i.e. a network under the one accreditation number), the response and supporting evidence must cover all of the sites (physical locations) covered by the accreditation. For such facilities, confirmation of compliance will occur during the assessment of the primary site (i.e. NPAAC category GX or S laboratory).

## **Authorised Representative declaration**

I declare to the best of my knowledge that the requirements of ISO 15189:2022 have been considered and implemented:

- a) at each site detailed in the table on page 2; and
- b) the information provided in this checklist together with the supporting evidence is applicable to each site detailed in the table on page 2.

Signature:	
Name:	
Date:	

**Facility and site details**

Facility accreditation number:	
Facility name:	
Indicate all applicable site numbers and names for multi-site facilities (If insufficient space, copy table and complete as necessary)	
Site number(s):	Site name (s):

ISO 15189:2022 Clause No.	Emphasis of Change	Action taken with reference to supporting evidence (as necessary) (Attach supporting evidence separately and include reference to the clause number)
4.2.2	New	
4.3	New	
5.4.1	Major	
6.2.3	Major	
6.7.2	New	
7.2.6.2	New	
7.2.7.3	New	
7.3.7.2	Major	
7.3.7.3	Major	
7.8	New	
8.1.2	New	
8.5.2	New	
Annex A - Only applicable if offering Point-of-Care Testing (PoCT)		
A.2	New	
A.3	New	
A.4	New	