IVD AUSTRALIA

The industry where innovation saves more Australian lives

Submission to the AS/NZS 4760:2017 Consultation on behalf of the IVD Industry in Australia, including Workplace Drug and Alcohol Testing Organisations

Table of Contents

About IVD Australia

IVD Australia is the peak body representing sponsors and manufacturers of in vitro diagnostics based in Australia.

Australia's leading pathology laboratory supply companies formed IVD Australia in July 2009 and we currently represent Australian manufacturers, multi-national and local distributors of pathology tests, as well as regulatory consultants working in the IVD sector. Our members currently supply products valued at over AUD 1.2 billion per annum and employ over 3,000 staff in multinationals, local distributors, local manufacturers, exporters and regulatory consultant companies; many of which are SMEs.

IVD Australia is a founding member of Pathology Awareness Australia, a group that represents interests across the entire field of pathology in Australia. This body is conducting the Know pathology, Know Healthcare Campaign on behalf of public pathology laboratories, private pathology companies, pathology professionals and manufacturers and suppliers to industry.

Executive Summary

On-site specimen collection and the qualitative detection of drugs is the preferred method of oral fluid testing in Australia. For over eleven years, Australian employers have favoured on-site testing of their employees as a workplace safety measure. Initially utilised in remote workplaces, on-site testing has grown to be accepted as the norm in most organisations undertaking a drug testing program, regardless of remote or metropolitan location.

On-site specimen collection and the qualitative detection of drugs (including alcohol) is a rapidly growing Australian industry that recognises the need for an Australian Standard to promote a consistently high-quality service to a growing number of Australian workplaces.

The draft Standard in its current format is not ready for final public consultation. Key issues identified in the 2006 standard have not been and cannot be rectified.

The key issues remain:

The standard was designed to sit within NATA's current standards.

NATA was unable to accredit workplaces without an on-site laboratory under AS 4760:2006.

NATA is the authority responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers throughout Australia (Source: https://www.nata.com.au/nata/about-nata).

Modifications to the current draft under consultation have been an attempt to correct the design flaws that would enable NATA to accredit on-site specimen collection and testing facilities as laboratories.

NATA will be unable to accredit workplaces without an on-site laboratory under the current draft standard.

A Standard that excluded the overwhelming majority of its current constituents should not be acceptable.

Should on-site collection and testing remain as a component, considerable rework will be required before it is acceptable to the on-site workplace drug and alcohol testing and IVD industries. Including but not limited to: reorganising of the appendices and informative and normative content; removal of incorrect statements; rewording of inappropriate statements; and limits/cut-offs that are applicable to on-site testing.

IVD Australia Recommendations

IVD Australia Recommendation 1

DR AS/NZS 4760:2017 be renamed **Off-site procedure for specimen collection and the detection and quantitation of drugs in oral fluid**.

IVD Australia Recommendation 2

The scope of the draft Standard AS/NZS 4760:2017 be refined to include only off-site laboratory-based detection and quantitation of drugs in oral fluid.

IVD Australia Recommendation 3

An Australian, and New Zealand, Standard for ***On-site procedure for specimen collection and screening for drugs in oral fluid*** be developed with the development committee comprised of on-site workplace drug and alcohol testing providers, users of the services and the IVD Industry, being the equipment suppliers.

Reworking the current DRAFT AS/NZS 4760:2017 to include on-site collection and testing

Key Requirements:

- Move the current "Appendix A On-Site Testing Procedure" to "Section 3 On-Site Initial Testing"
- Move the current "Section 3 General Laboratory Requirements" to "Appendix A General Laboratory Requirements", except where it duplicates the requirements of ISO 15189, in which case, these clauses should be removed and replaced with reference to the Standard.
- Remove Appendix C in its entirety; or re-label to remove any reference to on-site / screening tests; or re-consult on Appendix C to provide a standard appropriate to on-site / screening tests.

If these key issues cannot be rectified by application of Section 4 (specifically Clause 4.1.2) in Standardisation Guide 006: Rules for the Structure and Drafting of Australian Standards, then IVD Australia recommends that all substantive standards relevant to on-site workplace drug and alcohol be removed from this standard and a separate appropriate standard be developed.

Quality Control

The on-site device and the quality controls shall be used and stored strictly in accordance with manufacturer's instructions. The collector shall ensure that no aspect of the procedure causes contamination of the specimens. Where the manufacturer's instructions are not followed, quality control, as set out in Appendix A3.3, shall be undertaken, and also when the following are applicable:

- non-standard collection, storage and transportation methods are used;
- in-house laboratory designed or developed methods are used;
- standard methods are used outside their intended scope;
- validated methods are subsequently modified.

The collection facility shall have a written protocol for ensuring the integrity of specimen results in the event of a proficiency testing failure.

Verification of Devices

It is inappropriate to apply an evidentiary laboratory standard to an on-site (screening). Transportation and storage devices should be verified as being fit for the purpose which they are used. The proposed verification process is inappropriately prescriptive for the range of potential devices, in terms of dilution factor and recovery performance. The performance of device should be verified against how they are used in the process of on-site testing.

Re-verification of devices is required and should be performed at intervals of no more than 60 months where there have been no changes to production or design that may affect performance.

Additional comments are provided in the accompanying tabulated response.