Memorandum of Understanding

between

the Commonwealth of Australia

and

the National Association of Testing Authorities, Australia

in relation to

In-House In Vitro Diagnostic Medical Devices

This Memorandum of Understanding is made on 2/9/ 2016

between the

COMMONWEALTH OF AUSTRALIA, as represented by the Therapeutic Goods Administration ABN 40 939 406 804 within the Department of Health

and the

National Association of Testing Authorities (NATA), Australia (ABN 59 004 379 748), a company limited by guarantee having its Registered Office at 7 Leeds Street, Rhodes, NSW, 2138.

["the Parties"]

RECITALS

A. The TGA has responsibilities under the *Therapeutic Goods Act 1989* (the Act), on behalf of the Commonwealth, for ensuring therapeutic goods (pharmaceuticals, including radiopharmaceutical medicines, complementary medicines, vaccines, and medical devices, including in vitro diagnostic medical devices (IVD medical devices)) available in Australia are of acceptable quality, safe and efficacious to use and are available in a timely manner.

B. NATA is Australia's national authority for accreditation of laboratories conducting tests, calibrations and measurements in a wide spectrum of technical fields and for accreditation of producers of certified reference materials. It is also a peak body for the accreditation of inspection bodies and proficiency testing scheme providers.

C. The TGA and NATA, in recognising the complementary nature of their respective responsibilities as regulator and laboratory accreditation authority and their core competencies, have reached an understanding about co-operating and exchanging information and material on matters relating to the accreditation of laboratories engaged in the manufacture of in-house in vitro diagnostic medical devices (IVD medical devices).

BACKGROUND

A. The IVD medical device regulatory framework being implemented between 1 July 2010 and 30 June 2017 is designed to ensure all IVD medical devices, including in-house IVD medical devices, undergo a level of regulatory scrutiny that is commensurate with the risks associated with their use.

B. Under the framework, IVD medical devices are regulated as a subset of medical devices. The legislative basis for uniform Australian controls over medical devices is the Act, the Therapeutic Goods Regulations 1990 (the TG Regulations) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the TG MD Regulations).

C. The IVD medical device regulatory framework has the following features:

- an IVD medical device classification scheme based on different levels of risk for each class of device;
- all IVD medical devices must comply with a set of essential principles for the quality, safety and performance of the IVD medical device;
- a choice of procedures (known as conformity assessment procedures), based on the risk classification, to be applied by manufacturers to demonstrate initial and on-going compliance with the essential principles;

- compliance with recognised international and Australian standards as a means to establish that the essential principles have been met and conformity assessment procedures have been applied;
- provision for post market activities, including compliance testing, adverse event reporting and recalls.

D. NATA accreditation is available to any laboratory undertaking tests on human samples. It is recognised that:

- all Medical laboratories undertaking Medicare rebated pathology tests are required to hold NATA/RCPA accreditation requiring compliance with the standard ISO 15189, *Medical laboratories – particular requirements for quality and competence*, as amended from time to time;
- NATA accreditation can be granted to Medical laboratories not undertaking Medicare rebated pathology tests for compliance with the standard ISO 15189, *Medical laboratories – particular requirements for quality and competence*, as amended from time to time;
- in conjunction with Assessment activities for ISO 15189, NATA undertakes an assessment of the manufacture and use of in-house IVD medical devices against the National Pathology Accreditation Advisory Council (NPAAC) standards including the NPAAC Standard, *Requirements for the Development and Use of In-House In Vitro diagnostic Devices*, as amended from time to time.
- NATA is able to assess laboratories (that are outside the scope of ISO 15189) that manufacture Class 1-3 in-house IVD medical devices for compliance with ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* and the NPAAC standard, *Requirements for the Development and Use of In-House In Vitro diagnostic Devices as amended from time to time*. Requests from laboratories for accreditation to ISO 17025 will be considered by NATA on a case-by-case basis.

E. With the need to minimise additional compliance costs and avoid duplication of effort, the regulatory requirements for in-house IVD medical devices utilise existing systems of laboratory oversight, so that laboratories are able to meet the applicable conformity assessment procedures for in-house IVD medical devices provided they maintain the required accreditation with NATA and comply with the NPAAC Standard.

F. Under these requirements, manufacturers of in-house IVD medical devices must apply the relevant conformity assessment procedures set out in Schedule 3 of the TG MD Regulations.

G. Under these procedures the manufacturer of Class 1-3 in-house IVD medical devices must:

a) implement procedures in relation to the application of a quality management system to the manufacture of the device;

b) provide information to the Secretary about the quality management system and the device;

c) establish and keep up-to-date a post market monitoring, reporting and corrective action system.

These procedures are set out in clause 6A.2 of Part 6A, Schedule 3 of the TG MD Regulations. In summary, the procedures require laboratories to do the following:

d) notify the TGA of Class 1-3 in-house IVD medical devices being manufactured as required by the TG MD Regulations (form and timeframe);

e) ensure that the laboratory in which the Class 1-3 in-house IVD medical devices are manufactured is accredited by NATA (or a conformity assessment body

determined by the Secretary) as meeting the requirements of ISO 15189 or ISO/IEC 17025; and

f) meet the NPAAC Standard.

H. To support an application for inclusion in the Australian Register of Therapeutic Goods (ARTG) where required, manufacturers of Class 4 in-house IVD medical devices must, either:

a) apply the conformity assessment procedures in Part 1, Schedule 3; or

b) apply the conformity assessment procedures in Part 6B, Schedule 3, of the TG MD Regulations.

I. Under the procedures set out in Part 6B, Schedule 3, the manufacturer of Class 4 in-house IVD medical devices, must:

a) implement a quality management system for the design, production, packaging, labelling and final inspection of the device;

b) prepare technical documentation in relation to the device;

c) establish and keep up-to-date a post market monitoring, reporting and corrective action system;

d) make a declaration of conformity in relation to that kind of device;

e) prepare and keep records in relation to the procedures.

Under the conformity assessment procedures in Part 6B, Schedule 3 of the TG MD Regulations, manufacturers of Class 4 in-house IVD medical devices used in relation to the manufacture of blood, blood components, plasma derivatives, human cell and tissue based therapeutic goods have the option of meeting the conformity assessment requirements either by:

f) ensuring that the laboratory is both accredited by NATA as a Medical laboratory meeting the requirements of ISO 15189, and meets the NPAAC Standard (clause 6B.3(2)(b)); or

g) the manufacturer holding a current TGA manufacturing licence and satisfying the requirements in the Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products (clause 6B.3(2)(a)).

If the Class 4 in-house IVD medical devices is not used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods, the laboratory in which the device is manufactured must be both accredited by NATA as a Medical laboratory meeting the requirements of ISO 15189, and meet the NPAAC Standard (clause 6B.3(3)).

IT IS HEREBY AGREED as follows:

Clause 1 – Definitions and how to interpret this MOU

1.1 In this MOU:

'Assessment activity' means on-site visits to conduct assessment, reassessment, and variation of accreditation scope or surveillance as well as off-site activities such as document review. Further information on these activities can be found in the *NATA Procedures for Accreditation* at www.nata.com.au

'ARTG' means the Australian Register of Therapeutic Goods maintained under the Act.

'Chief Executive' means the Chief Executive of NATA and includes any person performing the duties of the Chief Executive.

'Contact Personnel' means the persons specified in clause 8 of this MOU.

'Deputy Secretary' means the person from time to time holding, occupying or performing the duties of the office or position of the Deputy Secretary responsible for the Health Product Regulation Group, Department of Health.

'In-house IVD medical device' has the same meaning as in the TG MD Regulations.

'ISO 15189' means the international standard titled ISO 15189, *Medical laboratories – Requirements for quality and competence* as amended from time to time.

'ISO/IEC 17025' means the international standard titled ISO/IEC 17025, *General requirement for the competence of testing and calibration laboratories,* as amended from time to time.

'IVD medical device or in vitro diagnostic medical device' has the same meaning as in the TG MD Regulations.

'Manufacturer of a medical device' has the same meaning as in the Act.

'Medical device' has the same meaning as in the Act.

'Medical laboratory' has the same meaning as in ISO 15189, *Medical laboratories – Requirements for quality and competence*.

'Laboratory network' has the same meaning as in the TG MD Regulations.

'NATA' means the National Association of Testing Authorities, Australia.

'NPAAC' means National Pathology Accreditation Advisory Council.

'NPAAC Standard' means the document titled *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices (IVDs)*, as amended from time to time.

'Parties' means the TGA and NATA and a 'Party' means either the TGA or NATA.

'Post Market Notification Requirements' means the post marketing notification requirements as set out in Parts 6A and 6B of the Conformity Assessment Procedures in Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 and in the NPAAC standard.

'RCPA' means Royal College of Pathologists of Australasia.

'TGA' means the Therapeutic Goods Administration, within the Commonwealth Department of Health.

'the Act' means the *Therapeutic Goods Act 1989*.

'the TG MD Regulations' means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

'the TG Regulations' means the *Therapeutic Goods Regulations 1990*.

1.2 Words in the singular include the plural and words in the plural include the singular.

Clause 2 - Required agreements

2.1 Where the Parties determine that the form, cost and timing of any activity within the Regulatory Objectives and Objectives of the MoU (see Clause 4) and Joint Undertakings (see Clause 5) of this Memorandum carries financial or other risks that are better managed using a formal legally binding agreement, the Parties will use their best endeavours to negotiate, draft and agree such an agreement for that purpose.

Clause 3 - General provisions

3.1 This MOU takes effect from the day of execution by both Parties and will continue unless terminated by either Party in accordance with the termination provision at clause 10.

3.2 The Parties agree to review the operation of this MOU at intervals not exceeding twelve months.

Clause 4 - Regulatory Objectives and Objectives of the MOU

4.1 The TGA's regulatory objectives are to protect public health through ensuring that only properly manufactured and validated in-house IVDs medical devices are used in laboratories and that these laboratories and devices meet appropriate standards as assessed by NATA, without the need for additional on-site assessment by the TGA.

4.2 The objectives of this Memorandum of Understanding are to:

(a) clarify the understanding of each party in relation to their roles, responsibilities and undertakings; and

(b) to formalise the arrangements for the exchange of information and material between the parties;

to facilitate the achievement of TGA's regulatory objectives in relation to in-house IVDs.

4.3 This Memorandum of Understanding has been developed and is to be implemented with the primary aim of ensuring that the above objectives (both regulatory and those of the MOU) are met. It is not intended to create a legal relationship between the parties.

Clause 5 - Joint Undertakings

5.1 To ensure that NATA's accreditation processes continue to align with the TGA's regulatory objectives, it is necessary for the Parties to ensure that:

(a) NATA is fully aware of the IVD medical devices regulatory framework as it applies to accredited laboratories manufacturing and using in-house IVD medical devices at any particular time;

(b) the TGA is fully aware of NATA's accreditation requirements and assessment processes at any particular time; and

(c) there is prompt communication between the parties on matters relating to the assessment of laboratories engaged in the manufacture of in-house IVD medical devices.

5.2 The TGA and NATA will facilitate effective communication on matters relating to this MOU. For ongoing liaison, the contact personnel identified under clause 8 will coordinate these activities.

5.3 The TGA and NATA will comply with any applicable legislation, such as the *Privacy Act 1988 (Cth)* in relation to any communications between the Parties.

5.4 The Parties will meet as often as is reasonably necessary to ensure the effective functioning of this MOU and, in any event, at least once a year to discuss issues that are relevant to, or arise from, the implementation or operation of the MOU. The Parties will cooperate to promptly identify any issues that arise from the implementation or operation of the MOU that may warrant clarification or change.

5.5 The Parties agree to exchange information on trends in technology and laboratory practice that have the potential to impact adversely their respective roles. This can include the provision of guidance and information on the clinical utility, misuse or performance of an in-house IVD.

5.6 The parties will use their best endeavours to resolve any divergence of views regarding the activities undertaken under this MOU. Unresolved divergences of views are to be resolved in accordance with the dispute resolution provisions in clause 9 of this MOU.

5.7 The TGA will facilitate the drafting of an instrument under subsection 61(5AB) of the Act to facilitate the provision of therapeutic goods information to NATA to support the operation of this MOU.

5.8 The TGA will provide to NATA copies of the legislation and any proposed amendments including the explanatory memorandum and other background materials to facilitate NATA's understanding of the legislation in undertaking its Assessment activities.

5.9 The TGA and NATA will cooperate to develop any operational procedures necessary to achieve the objectives of this Memorandum of Understanding.

Clause 6 - NATA Undertakings

6.1 In the course of any Assessment activities undertaken in relation to accreditation, NATA will require the laboratory to identify any in-house IVD medical devices being manufactured.

6.2 NATA will include all in-house IVD medical devices identified and put forward by the laboratory for assessment in the scope of the Assessment activities.

6.3 NATA will apply all the relevant Clauses of ISO 15189 or ISO/IEC 17025, for the purpose of undertaking an Assessment activity to assess compliance of a laboratory that manufactures in-house IVD medical devices.

6.4 NATA will, for the purpose of undertaking an Assessment activity to assess compliance of an in-house IVD medical device with the NPAAC Standard:

(a) for an in-house IVD that has not previously been assessed, focus on the requirements relating to design, production and technical validation aspects (sections 2 – 7) and the relevant documentation requirements (section 11).

(b) for an assessment of any other in-house IVD, focus on the requirements relating to monitoring, analysis and improvement (section 9), adverse event reporting and recalls (section 10) and the relevant documentation requirements (section 11).

6.5 When NATA undertakes an Assessment activity to assess compliance of an in-house IVD medical device with the NPAAC Standard it will:

(a) where it is a Class 1 or 2 in-house IVD medical device - apply a risk-based sampling approach to assess its manufacture and performance;

(b) where it is a class 3 in-house IVD medical device – assess its manufacture and performance; and

(c) where it is a Class 4 in-house IVD medical device – examine aspects of manufacture and performance not already assessed by the TGA.

6.5 Where NATA undertakes an Assessment activity at a laboratory that:

(a) is a subordinate site in a Laboratory network; and

(b) uses one or more in-house IVD medical devices manufactured by the primary laboratory of the network;

NATA will verify that the in-house IVD medical device is being used in accordance with its intended purposes and in the manner prescribed by the primary laboratory.

6.6 In undertaking an Assessment activity in relation to a laboratory that manufactures an in-house IVD medical device, NATA will assess that the laboratory has implemented a post-market system that:

(a) monitors the performance of that in-house IVD medical device to systematically review experience gained in the post-production phase for the device; and

(b) implements corrective action as appropriate to address deficiencies in design and production and includes procedures for recovery of any of the in-house IVD medical devices that have been distributed within a Laboratory network; and

(c) includes a system for notifying the TGA of any adverse events arising from the use of the in-house IVD medical device.

6.7 NATA will, upon becoming aware of an issue with a non-conformance by the laboratory with the Post Market Notification Requirements in relation to the manufacture or performance of an in-house IVD medical device, promptly provide the TGA with the following information, as relevant, such as:

(a) information relating to problems with the manufacture and monitoring of the performance of an in-house IVD medical device and any other affected in-house IVD medical device manufactured by that laboratory;

(b) progress in addressing non-conformance issues for the laboratory where it has previously been identified by NATA as having problems in relation to these activities;

(c) any suspension, cancellation, variation to the scope of accreditation or any other decision affecting accreditation of the laboratory that involved or impacted upon the in-house IVD medical device.

6.8 NATA may seek advice from its expert committees and/or advisers in order to determine whether an issue "represents a serious risk to public health or has led or may lead to the death or serious deterioration in the state of health" for the purposes of clause 6.7.

6.9 NATA will respond promptly to concerns raised by the TGA with respect to the performance or competence of NATA accredited laboratories and will provide timely feedback on actions taken by NATA or the laboratory to address those concerns.

6.10 If NATA becomes aware that a laboratory has manufactured one or more Class 1-3 in-house IVD medical devices that have not been notified to the TGA, NATA will advise the laboratory of the requirements of the TG MD Regulations; including that the laboratory is required to notify the TGA of their in-house IVD medical devices under clause 6A.2, Part 6A of Schedule 3 to the TG MD Regulations.

6.11 If NATA becomes aware that a laboratory has manufactured one or more Class 4 in-house IVD medical devices not included in the ARTG that appear not to be exempt from this requirement, it will:

(a) advise the laboratory immediately of the requirements of the TG MD regulations, to desist from manufacturing and using the device and to immediately notify the TGA;

(b) promptly provide the TGA with the information regarding the laboratory and Class 4 in-house IVD medical devices.

6.12 NATA will keep the TGA informed of any impending change to its procedures and accreditation criteria that would impact on laboratories' ability to comply with the requirements of the IVD medical device regulatory framework.

Clause 7 – TGA Undertakings

7.1 The TGA will actively engage with stakeholders that are, or might become, involved in the manufacture of in-house IVD medical devices to increase awareness of the IVD medical device regulatory requirements in the Act and the TG MD Regulations. In particular, the TGA will publish information to clearly describe laboratories' obligations under and procedures for complying with the TG MD Regulations. This will include:

(a) the need for laboratories to obtain NATA accreditation for ISO 15189, or ISO/IEC 17025 as appropriate;

(b) the need to comply with the NPAAC Standard;

(c) the need for laboratories to declare to NATA, prior to any Assessment activity, if they are manufacturing in-house IVD medical devices subject to the regulatory requirements.

7.2 On request by NATA, the TGA will provide the following information to assist NATA to prepare for an Assessment activity for a particular laboratory:

(a) a list of Class 1-3 in-house IVD medical devices manufactured by the laboratory and the date the most recent notification under Schedule 3, Part 6A, clause 6A.2 of the TG MD Regulations was made to the TGA by that laboratory;

(b) a list of any Class 4 in-house IVD medical devices manufactured by the laboratory that are included in the ARTG;

(c) details of any regulatory decisions made in respect of an in-house IVD medical device manufactured by that laboratory; and

(d) details of any post-market investigations undertaken in respect of an in-house IVD medical device manufactured by that laboratory.

7.3 The TGA, upon being notified by a laboratory about the manufacture and/or use of in-house IVD medical devices that is required under the post-market system will promptly communicate this to NATA.

7.4 The TGA will ensure that NATA is promptly advised in writing of any impending change to the IVD medical device regulatory requirements that would impact on its accreditation activities or in relation to NATA's obligations under this MOU.

7.5 Where appropriate, the TGA will provide training to relevant NATA staff on the operation of the IVD medical device regulatory requirements and any anticipated impacts that this might have on accreditation assessment activities.

7.6 The TGA will provide timely advice to NATA upon becoming aware of matters that may be relevant to the performance or competence of laboratories covered by this MOU.

7.7 If requested by NATA, the TGA will, to the maximum extent possible, assist NATA in furtherance of the work of its accreditation advisory committees in relation to the assessment of laboratories engaged in the manufacture of in-house IVD medical devices. Where officers of the TGA assist NATA in these activities, no recovery will be sought for the salary and salary-related costs involved.

7.8 Where officers of the TGA assist NATA as technical (peer) assessors, no recovery will be sought for the salary and salary-related costs under normal circumstances. Where the burden on the TGA entity is such that its own activities could be compromised, restrictions on availability may be applied.

Clause 8 - Contact Personnel

8.1 All communications between the TGA and NATA relating to interpretation and variations to this MOU will be between, in the first instance:

For the TGA:

Position: Assistant Secretary, Medical Devices Branch
Address: TGA
PO Box 100
MDP 122
WODEN ACT 2606
Tel No: 02 6232 8444
Fax No: 02 6232 8605

For NATA	Position:	Chief Executive
	Address:	NATA PO Box 7507 SILVERWATER NSW 2128
	Tel No:	02 9736 8222
	Fax No:	02 9743 5311

8.2 All communications between the TGA and NATA relating to joint operational procedures necessary to achieve the objectives of this Memorandum of Understanding will be between, in the first instance:

For the TGA:	Position:	Director, IVD Reforms, Medical Devices Branch
	Address:	TGA PO Box 100 MDP 122 WODEN ACT 2606
	Tel No:	02 6232 8281
	Fax No:	02 6232 8605
For NATA	Position:	Deputy Sector Manager – Legal and Clinical Services
	Address:	NATA Level 1, 2-6 Railway Parade Camberwell, Victoria 3124
	Tel No:	03 9274 8200
	Fax No:	03 9421 0887

Clause 9 - Dispute Resolution

9.1 If any dispute relating to this MOU arises, the TGA and NATA Contact Personnel will endeavour, in good faith, to resolve the dispute expeditiously and amicably within agreed timeframes.

9.2 If any dispute is not so resolved within the agreed timeframe, it is agreed that the matter in dispute will be escalated to the Deputy Secretary and the CEO to resolve the dispute within an agreed timeframe in a manner that is consistent with good administration.

9.3 Each Party agrees to continue to meet its obligations under this MOU notwithstanding the existence of a dispute.

Clause 10 - Termination

10.1 Either Party may terminate this MOU by giving 30 days advance notice in writing (the relevant period) to the other Party.

Clause 11 - Variation

11.1 This MOU may be varied by the mutual consent in writing by both Parties.

11.2 Contact details identified in Clause 8 will be updated as required and notified in writing to the other party.

MOU signatories

SIGNED for and on behalf of the
Therapeutic Goods Administration

By Adjunct Prof John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Date: 19/08/2016

SIGNED for and on behalf of the
National Association of Testing Authorities, Australia

By Mr Alistair Ross AM
Chair
National Association of Testing Authorities, Australia

Date: 02/09/2016