Australian Government

Department of Industry, Innovation and Science

DISCUSSION PAPER:

TRACEABLE **MEASUREMENT**

Measurement Law Review

2019

Have your say

The Australian Government is seeking responses to the issues and questions raised in this paper. You can submit your comments via the Department of Industry, Innovation and Science's Consultation Hub https://consult.industry.gov.au/measurement-law-review/measurement-in-everyday-life

Australia's measurement laws can be found on the Federal Register of Legislation **https://www.legislation.gov.au**.

Submissions will be considered by the government to finalise options for reform.

If you have difficulties or questions, please call **1300 686 664** or email **measurementlawreview@industry.gov.au**.

The closing date for submission is **31 May 2019**.

Submissions received may be made public on the consultation website unless otherwise specified. Submissions should indicate whether any part of the content should not be disclosed to the public.

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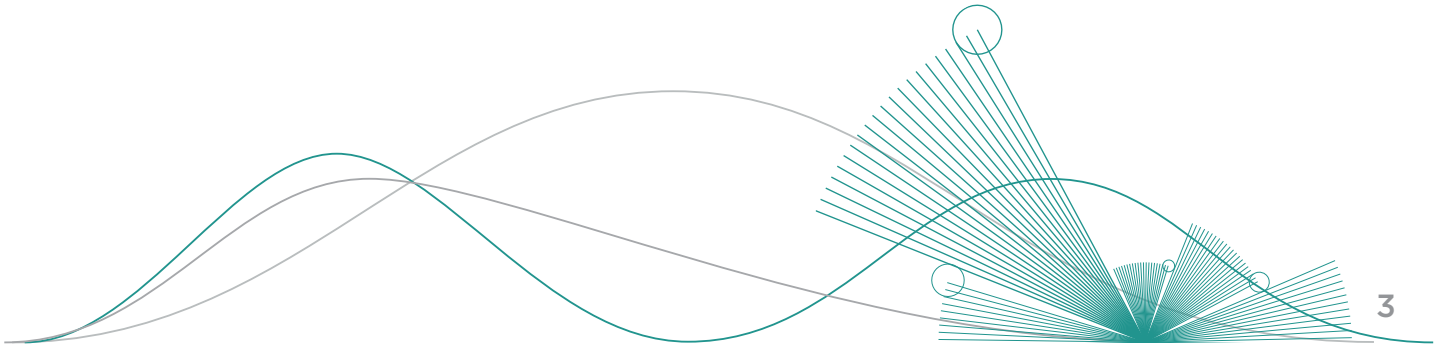


DISCUSSION PAPER:

TRACEABLE **MEASUREMENT**

MEASUREMENT LAW REVIEW – DISCUSSION PAPERS

1. Overview

Measurement plays an important role in Australia's economy. As detailed in section 51(xv) of the Constitution, the Australian Government has responsibility for weights and measures and, in keeping with this responsibility, has enacted legislation to carry out its metrological functions. The objectives of this legislation include establishing and coordinating a uniform national system of measurement, including trade measurement.

A 2015 independent review of Australia's legal metrology activities indicated while the national measurement system is working well, the legislation is:

- very prescriptive and needs to address matters of policy and principle, reduce prescription and remove matters of detail (regulatory processes) into subordinate legislation or guidance material
- complicated and needs to enable the public to understand their obligations and the implications of regulatory measurements, and
- not easy to understand and needs to be written in plain language to improve clarity and simplicity.

The measurement law needs to: better reflect and integrate current policy and principles into the legislation; articulate performance outcomes; and enhance flexibility, with consideration given to the application of a principles-based approach.

1.1 The Measurement Law Review (The Review)

The Australian Government is conducting a review of Australia's measurement laws. The Review aims to ensure Australia's measurement framework can support the economy now and into the future as technology, industry and consumer needs evolve.

The Review provides an opportunity to consider whether the legislation continues to be appropriate, effective and efficient. This paper is not an exhaustive exploration of the topic and you are welcome to raise issues and views not outlined in this paper in your submission. Questions are provided at the end of each section to prompt feedback. Any calculations of costs or benefits to any issues raised would be useful to include in your submission.

The Review secretariat would be interested in receiving responses from parties including, but not limited to:

- a person or entity involved in making or relying on measurements under the legislative framework
- providers of physical, chemical and/or biological measurement services
- providers of measuring instruments
- innovators of measurement technology
- jurisdictional agencies whose regulations call up measurement laws
- legal professionals
- consumers and the general public who rely on or are impacted by measurement in their daily lives.

For more information on the Review, please visit **www.industry.gov.au/measurement-law-review**.

1.2 This Discussion Paper

The Review secretariat seeks insights into the role of government and viable approaches to assure traceable measurement where required. The secretariat seeks views on streamlining the existing framework that provides legal validity to measurements.

A legal framework aims to give greater assurance that measurements are indeed what they purport to be and that they can be ascertained in case of dispute.

It should be noted that this paper is focused on Australia's legal measurement system. Measurement required for compliance with International Laboratory Accreditation Cooperation (ILAC), National Association of Testing Authorities, Australia (NATA), International Organization for Standardization (ISO) or other international standards bodies, or for operational and quality needs, remains largely unaffected.

This discussion paper on Traceable Measurement will refer to:

- The *National Measurement Act 1960* (the Act), Part II: Units and standards of measurement
- The *National Measurement Regulations 1999* (NMR), Parts 3 (Standards of measurement), 3A (Artefacts), and 5 (Reference Materials)
- The *National Measurement Guidelines 2016*
- All Determinations issued under the Act.

This paper covers traceable measurement of physical quantities with considerations for chemical and biological quantities in the context of the legal measurement system.

For additional information on all discussion papers, please refer to the ***Guide to the Discussion Papers***.

2. Traceable measurement

The internationally accepted definition of traceability is:

> *Traceability refers to the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.*[1]

Measurement science provides the basis by which measurements of physical, chemical or biological quantities may be made with known uncertainties.

The current metrological functions of the Commonwealth include, among other things, to:[2]

- adopt and realise units of measurement
- develop and maintain standards of measurement, reference materials and reference techniques
- promote best practice in measurement
- provide expertise to support the Australian standards and conformance infrastructure
- provide measurement services to industry, scientific organisations and government, and
- conduct research.

While the above functions contribute to measurement traceability, the legislation does not use the word 'traceable' or 'traceability'. Instead, words that invoke the concept are used, including 'ascertain' and 'verify'.

As a signatory to the Metre Convention, Australia adheres to the International System of Units (SI).[3,4] The core of SI-traceable measurement results is an unbroken link from reference standards defined by SI units to practical measurements. In reference to the SI, the highest accuracy national standards of measurement of physical quantities are realised[5] by the Australian Government through the National Measurement Institute (NMI). These standards are maintained, propagated and disseminated for use throughout the Australian economy; for example, the unit for mass, the kilogram, is maintained over the range 1 mg to 1000 kg to support the needs of the economy.

Chemical and biological measurements are also used throughout the economy, including for healthcare, food safety, law enforcement and environmental monitoring. Confidence in chemical and biological measurement is underpinned by the use of certified reference materials (CRMs). NMI produces CRMs and develops high-accuracy reference measurement procedures.

A CRM of the major metabolite of testosterone, with certified purity, is produced by the NMI. Anti-doping laboratories around the world calibrate their analytical instruments using a CRM. These instruments compare the extract from an athlete's urine to the reference material. The instruments also identify whether the detected substance is testosterone and then measure the amount of testosterone in the urine. Trusted measurements using CRMs enable effective anti-doping controls in sport.

1 JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd edition 2008 version with minor corrections, at 2.41 (6.10) including Notes 1-8.

2 Section 18 of the Act.

3 As of November 2018, the Metre Convention included 59 member states and 42 associate states and economies. See https://www.bipm.org/en/about-us/member-states/

4 For information on the SI, see https://www.bipm.org/en/measurement-units/

5 Glenda Sandars, Traceable Measurements, Monograph 3: NMI Technology Transfer Series, NMI, 4th edition, Nov 2005: "SI units are of little use unless they can be represented by physical standards. This process is often referred to as realising (literally, making real) the units. It is a demanding task to produce a definitive standard for each unit, and the process may involve many years of research, usually undertaken by national metrology institutes around the world."

The competence, capability and practices of entities involved in providing measurement services in Australia are supported through the standards and conformance system. This involves NMI collaborating with: the entity that issues documentary standards, Standards Australia; the body that accredits laboratories and technical facilities, the National Association of Testing Authorities (NATA); and the body that accredits certification and/or inspection bodies, the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).

3. Legal measurement system

The Act establishes a single,[6] national legal measurement system for trade and non-trade (legal) purposes.[7] Mechanisms for achieving traceability for legal and trade measurements are described in the Act. Most of the text in the Act itself prescribes matters relevant to legal and trade measurement.

Ensuring measurements used in trade are defensible is a key objective of the legal measurement framework. The Act establishes a framework for ensuring that measuring instruments used for trade are verified, used in a way that gives an accurate measurement, and are accurate in themselves. The Act establishes the related offences for non-compliance.[8]

The Act also aims to ensure that chemical and biological measurements carried out on traded commodities, such as natural gas or food, are traceable. Currently, however, there is a narrow scope of recognition of CRMs in the Act, which is discussed later in the paper.

Measurements can be used for other legal purposes besides trade. The Act therefore establishes mechanisms for the approval of a measuring instrument and for its certification to demonstrate traceability under the Act,[9] for purposes such as law enforcement measurements. For example, traffic speed measurements that directly inform penalties for excess speed and breath alcohol concentration measured by Evidential Breath Analysers (EBAs) that determine an offence related to drink-driving if alcohol concentration exceeds certain levels).

The Review secretariat seeks views on the appropriateness, effectiveness and efficiency of the legal framework in giving legal validity to measurement.

6 Jan Todd, 2004, *For Good Measure*, page 176. Australia previously had five measurement systems with a total of 29 basic units of measurement. These measurement systems included: avoirdupois; troy; apothecaries; metric; and metric carat. There are now 7 units of basic measurement, as provided in Part 1 of Schedule 1 of the NMR.

7 Second Reading Speech, National Measurement Amendment Bill 2003, 3 December 2003. Second Reading Speech, National Measurement Amendment Bill 2008, 24 September 2008.

8 Issues in regard to enforcement and non-compliance with measurement laws will be dealt with in the Compliance Arrangements discussion paper, which will be released on the Review's website at a later time in 2019.

9 Sub-paragraph 19A(1)(b)(ii) of the Act provides that *'[t]he regulations may make provision for or in relation to (b) the approval and verification of patterns of measuring instruments as patterns of measuring instruments suitable for: (i) use for trade and (ii) any other legal purpose'*.

3.1 Current approach

The legal measurement system uses the following mechanisms to make measurements traceable and legally defensible:

- use of standards of measurement which are traceable to the national standards[10]
- legal units of measurement using agreed terminology[11]
- provision to verify standards of measurement[12]
- provision to certify a reference material[13]
- appointment of competent authorities to verify standards of measurement and physical quantities of artefacts[14]
- appointment of competent authorities to certify measuring instruments used for legal purposes[15]
- appointment of servicing licensees to verify measuring instruments used for trade,[16] and
- issuing of certificates as legal documents attesting that measurements are traceable to specific standards with their uncertainties, and the fixing of marks to signal legal validity.

To facilitate traceability for trade measurements, the Act allows for persons to be licensed (Servicing Licensees) to verify measuring instruments used for trade by testing with reference to weights and measures traceable to national standards.[17] Further discussion on this will be covered in the discussion papers: *Measuring Instruments* and *Third-Party Arrangements*[18].

Traceability for measurements used for non-trade purposes is typically achieved by using the services of NATA or ILAC-accredited laboratories whose standards of measurement are traceable to NMI or its international counterparts with Calibration and Measurement Capabilities internationally recognised through the CIPM Mutual Recognition Arrangement (CIPM MRA).[19] However, in developing areas (e.g. nanotechnology) or areas requiring extremely low uncertainty or highly specialised capabilities, NMI may also develop and deliver these services.

Commonwealth, State or Territory legislation may require measurements to be ascertained in accordance with the requirements under the Act or in other ways. The measurement framework is fundamental for other regulators and at least 80 Commonwealth, State and Territory laws to meet their policy objectives by referencing measurement infrastructure overseen by the Act. Non-legislative instruments also refer to measurement laws and regulations for diverse purposes in, for example, policy documents, guidelines and directives. In the event of a dispute, the courts decide whether to accept measurements as evidence and whether a measurement needs to be ascertained by reference to the Act.

10 Part II of the Act.
11 These legal units of measurement are provided for in Schedules 1 and 2 of the NMR.
12 Part 3 of the NMR.
13 Part 5 of the NMR.
14 Part 3A and regulation 73 of the NMR. Section 3 of the Act defines 'artefact' to mean *'a physical object that is not a standard of measurement'*.
15 Part 4 and regulation 73 of the NMR.
16 Part X and section 18GH of the Act.
17 Section 18GH of the Act.
18 The Third-Party Arrangements discussion paper will be published in the Review's website at a later time in 2019.
19 More details can be found in ILAC's policy on Traceability of Measurement Results and NATA's Metrological Traceability policy with principles aligning with that of ILAC.

3.2. Issues and questions

3.2.1 The need for a provision that specifies how measurements are to be ascertained when, for any legal purpose, it is necessary to determine whether a measurement has been made or is being made correctly with reference to Australian legal units of measurement (ALUM).

Section 10 of the Act prescribes the manner of ascertaining whether a measurement has been made, or is being made, correctly with reference to an ALUM. This provision only includes using an appropriate standard of measurement, an Australian Certified Reference Material (ACRM), a certified measuring instrument, a combination as provided in Section 10 of the Act, and not in any other manner.[20] The Section excludes pathways to traceability that may emerge from advances in science and technology.

QUESTIONS

3.2.1.a How effectively have you been guided by this provision in the Act?

3.2.1.b What alternative mechanisms or frameworks could be used to determine whether a measurement is being made correctly with reference to an ALUM?

3.2.2 Mechanisms of legal assurance for a measurement system applied broadly to non-trade purposes

Mechanisms used for trade may be used for purposes other than trade, for example the use of weighbridges regulated under the Act to support the safe loading of cargo on ships to meet Australian Maritime Safety Authority requirements.[21]

QUESTION

3.2.2.a In what ways can the Australian Government make traceability assurance mechanisms more accessible for non-trade measurement purposes (for example environmental monitoring, safety, health and medical devices)? What efficiencies or benefits would be achieved by doing so?

20 The Act, Section 10: *When, for any legal purpose, it is necessary to ascertain whether a measurement of a physical quantity for which there are Australian legal units of measurement has been made or is being made in terms of those units, that fact shall be ascertained by means of, by reference to, by comparison with or by derivation from: (a) an appropriate Australian primary standard of measurement; (b) an appropriate Australian secondary standard of measurement; (c) an appropriate State primary standard of measurement; (d) an appropriate recognized value standard of measurement; (e) an appropriate reference standard of measurement; (f) 2 or more standards of measurement, each of which is a standard of measurement referred to in paragraph (a), (b), (c), (d) or (e); (g) an Australian certified reference material; (h) a certified measuring instrument; (i) one or more standards of measurement, each of which is a standard of measurement referred to in paragraph (a), (b), (c), (d) or (e) and an Australian certified reference material; (j) one or more standards of measurement, each of which is a standard of measurement referred to in paragraph (a), (b), (c), (d) or (e) and a certified measuring instrument; or (k) one or more standards of measurement, each of which is a standard of measurement referred to in paragraph (a), (b), (c), (d) or (e), an Australian certified reference material and a certified measuring instrument; and not in any other manner.*

21 See, for example, ***Marine Order 42 (Carriage, stowage and securing of cargoes and containers) 2016 section 10*** (*Verification of gross mass of cargo units and cargo carried in certain containers [SOLAS VI/2]*).

4. Traceable measurement of physical quantities

The Australian Government legislates measurement of physical quantities due to the broad applications of physical measurement in the economy and society.[22] 'Physical quantities' is a term used in the current Act; it also covers chemical and biological measurements which are explored in the next section.

4.1 Current approach

The current measurement legislation establishes, among other things, the units and standards of measurement for physical quantities, establish a formal basis for measurement accuracy[23] and provide for their uniform use throughout Australia.

The legislation refers to scientific definitions of measurement and specifies their use. Key among these are prescribed units and standards of measurement[24] and the maximum permissible uncertainties for these standards of measurement.[25] The legislation generates legal assurance and communicates confidence in measurement through specific traceability requirements such as the verification of standards of measurement[26] by appointed competent authorities[27] and recording in a certificate the measurement result with a statement of its accuracy.[28]

The ALUMs for a physical quantity are prescribed in legislation.[29] They include:

- the SI base units:
  - kilogram (kg) for mass
  - second (s) for time
  - ampere (A) for electric current
  - metre (m) for length
  - candela (cd) for luminous intensity
  - kelvin (K) for thermodynamic temperature
  - mole (mol) for amount of substance

22 Second Reading Speech, the Senate, Weights and Measures (National Standards) Bill 1960, 15 November 1960, paragraph 5: "The words 'weights and measures', although thought of normally as referring to those weights and measures used in commercial transactions, apply to standards of measurements of all physical quantities used in commerce, industry and science..."

23 This is achieved through a clear statement of maximum permissible uncertainty for standards of measurement, as outlined in Schedules 4 through 10 of the NMR.

24 The Act Part II (Units and standards of measurement), NMR Part 2 (Units of measurement), Part 3 (Standards of measurement), Part 3A (Artefacts)

25 NMR Schedules 4-10.

26 NMR Part 3 (Verification of standards of measurement) regulations 11-15.

27 NMR Part 7 (Authorities); Part 8 (Dealing with verification, certification, approval and appointment other than on application).

28 NMR Part 3 (Marks and certificates of verification; When verification ceases to have effect and may be cancelled; Accuracy, value and uncertainty of standards of measurement) regulations 16-34.

29 The Act Part 2 (Units and standards of measurement) section 7, 7A and 7B; NMR, Schedules 1 – 3; see also National Measurement Guidelines 1999.

- SI-derived units (e.g. hertz (Hz) for frequency)
- some non-SI units used with SI units (e.g. hectare (ha) for area; knot (kn) for velocity)
- additional derived units of measurement (e.g. volt ampere hour (VAh) for apparent energy)
- additional units of measurement for use in particular purposes (e.g. foot (ft) for length may be used for the purpose of measuring altitude and vertical separation in aviation, or submarine depth).

NMI realises measurement units from their definitions, maintains appropriate standards of measurement and under the CIPM MRA participates in coordinated programs of comparisons with standards maintained by international counterparts. These activities establish the comparability and international recognition of Australia's measurement standards and measurement capabilities. As a result, these activities contribute to reducing the technical barriers to international trade.

The Commonwealth additionally appoints third parties (Verifying Authorities, Certifying Authorities) with the relevant competence to provide traceable measurements which contribute to ongoing accuracy of measurement. Their roles include, for example:

- verification of reference standards of measurement and physical quantities of artefacts, and
- certifying reference materials or measuring instruments.

Third parties communicate the traceability of measurements through certificates issued under the Act.

Example of traceable measurement in practice:

The traceability of a physical quantity is evidenced through certificates issued by NMI to, for example, calibration laboratories. These certificates attest to the accuracy of the reference standards used by calibration laboratories (for example a gauge block, mass sets, and thermometers). The certificates under the Act provide assurance that measurements are checked against reference standards and are what they purport to be. Certificates are accepted as evidence in courts of law.

4.2 Issues and questions:

4.2.1. Prescriptiveness of legislation

In 2015, a review of Australia's legal metrology activities found the legislation to be overly prescriptive, and recommended that it could be modernised and streamlined using best practice regulatory frameworks.

QUESTIONS

4.2.1.a. What elements of the measurement framework are currently too prescriptive?

4.2.1.b. How and where should flexibility be incorporated to ensure the framework is both robust but also adaptable into the future?

4.2.1.c. How could a principles-based approach be implemented for traceability of measurements of physical quantities?

4.2.2. Traceability of measurement results from self-calibrating devices:

In recent years, there has been an increase in instruments that claim to self-calibrate against a built-in reference. For example, there are: weighing instruments that have inbuilt technology to self-calibrate for ongoing accuracy; temperature sensors that are claimed by manufacturers to "self-calibrate" and digitally store a calibration history; flowmeters that use big-data, Artificial Intelligence (AI) and cloud-data techniques to provide "health-check" assurances of ongoing accuracy.

QUESTIONS

4.2.2.a. What legal assurances should be in place to provide confidence in self-calibrating devices?

4.2.2.b. In what circumstances should inbuilt references for self-verifying instruments be traceable?

4.2.2.c. How would verification of built-in references assure traceability for self-calibrating devices? What should this approach look like?

4.2.2.d. How important is it for the user to know whether a manufacturer's claims that devices are self-calibrating are supported and accepted by the legal framework? Please give an example.

4.2.2.e. What should be the government's role in assuring traceability of built-in references to self-calibrating instruments?

4.2.3. Traceability of measurement results associated with new technologies

The internet and digital technologies have increasingly been changing the way we do many things, including measurements. The value of data flows traded as of 2015 nearly matched that of the global trade in physical goods.[30] Innovations are driven by technologies, such as the Internet of Things (IoT) and cloud computing. These technologies enable data flows across national borders. Physical objects are increasingly being integrated into the global information network through sensors that may be connected to servers in another country. The user might not know whether measurement results are traceable to internationally agreed standards of measurement (e.g. the SI) and/or whether verification is done through a framework outside the Australian jurisdiction. In addition, underlying data and algorithms are often owned by the manufacturer and may be subject to ongoing change outside the control of the user.

QUESTIONS

4.2.3.a. Is the current standards and conformance infrastructure meeting your traceability needs?

4.2.3.b. Are you or your customers concerned about security, authenticity and integrity of measurement results associated with new technologies and their source of traceability?

4.2.3.c. How can confidence in measurements based on new and advanced technologies be supported by the measurement framework?[31]

4.2.3.d. Have you encountered any barriers to adopting new technologies arising from the current measurement law framework?

30 https://www.mckinsey.com/mgi/overview/in-the-news/the-ascendancy-of-international-data-flows "We found that, since 2005, the volume of data flows, measured in terabits per second, has multiplied … More crucially, and in part driven by the material growth in cross-border data bits internationally, the value of data flows has nearly matched the value of global trade in physical goods. By 2014, cross-border data flows accounted for $2.3 trillion of this value, or roughly 3.5% of total world GDP."

31 Metrology clouds are proposed by some national measurement institutes and manufacturers as a trustworthy core platform for a digital quality infrastructure. See example in https://www.ptb.de/cms/nc/en/research-development/challenges-and-future-prospects/metrology-for-the-digitalization.html

4.2.4. Mechanisms of legal assurance for a national measurement system

There is a reliance on verification or certification, delivered by third parties, for the legal assurance of traceable measurement. These apply to instruments within the scope of the legislation.

QUESTIONS

4.2.4.a. Does verification or certification appropriately deliver on assuring traceability and confidence in measurement results for measurements used for trade and other legal purposes?

4.2.4.b. What other approaches or mechanisms could be used to assure traceability and provide confidence in measurement results?

4.2.4.c. Does your industry face measurement traceability problems? If so, what is the impact of these problems?

4.2.5. General matters

QUESTIONS

4.2.5.a. In what additional ways could the legislation be amended to support and enable traceability relating to physical quantities?

4.2.5.b. What costs are incurred by your business as a result of the current requirements?

4.2.5.c. How could current arrangements be made more efficient?

5. Traceable measurement of chemical and biological quantities

Amendments to the Act in 2003 brought chemical and biological measurement into the legislation and within the functions of NMI. The amendments recognised the important role of chemical and biological measurement in the economy.[32] It included among the Australian Government's metrological functions those that support and enable an approach to traceability relating to chemical and biological quantities.[33]

5.1 Current Approach

Traceability to the SI units of the mole and kilogram are typically used to establish the quantity of a chemical or biological entity. It should be noted that traceable measurements in this area include not only the quantity but also other aspects such as the identity and activity of the chemical or biological substance.

A 'certified reference material' (CRM) is a widely-used generic term in the field of science which also has a particular meaning in jurisdictions outside Australia. CRMs are used for the calibration of instruments and they are crucial to the traceability of chemical and biological measurements. They also have roles such as the validation of analytical methods.

CRMs have widespread usage including testing related to enforcement programs, for example illicit drug seizures or imported food inspections. State authorities and local government authorities also have enforcement programs and can bring legal action based on measurement results which are provided based on a CRM.[34]

An important aspect for consideration in the field of chemical and biological measurements is that nearly all CRMs currently used in Australia are not recognised under the Act.

32 Second Reading Speech, National Measurement Amendment Bill 2003, 3 December 2003, at paragraph 31 provides "*The decision to create a National Measurement Institute and to bring chemical and biological measurement into the functions of the institute and into the legislation underlines the contemporary importance of these measurement functions for innovation in industry and trade. It also highlights the increasing need for more rigorous metrological principles to be applied to chemical and biological measurement.*"

33 Explanatory Memorandum, National Measurement Amendment Bill 2003, House of Representatives, at item 11 (d) provides "*The National Measurement Institute will promote understanding of and the application of best practice in measurement. For example, it will promote the use of certified reference materials, where they exist, as standards for chemical measurement.*"

34 The policy intent (as stated in the National Measurement Amendment Bill 2010 – Explanatory Memorandum, Schedule 1, items 4 and 5) was to replace CRM with ACRM. "*.. removes the term 'certified reference material'. The latter term is in use in jurisdictions outside Australia as well as being widely used in a generic term in the field of science. This may cause some stakeholder confusion about compliance with obligations under Australian law, particularly when using imported products available in Australia and which are described as certified reference materials in their jurisdictions of origin.*"

5.1.1. Australian Certified Reference Materials (ACRMs)

Under Australia's measurement law, there is a distinction between:

- reference materials which have been certified in accordance with the legislation, known as ACRMs, and which have a particular legal purpose under the Act, and
- reference materials which have been certified but not in accordance with the legislation, and which have widespread usage for scientific and other purposes – being CRMs.

ACRMs are produced and formally recognised under Regulation 48 of the Act where there is value in the CRM having special legal standing.[35] They are currently only produced in a very small number of cases. In the event of a dispute or court proceeding, a Regulation 48 certificate provides confidence under the legislation.

In addition to allowing NMI to develop ACRMs,[36] the measurement framework under the current legislation allows the Chief Metrologist to formally recognise foreign certified reference materials as ACRMs[37] and issue a written notice giving them Australian legal status under Regulation 48. However, this only occurs currently in a limited number of cases.

The legislation also enables third parties to function as certifiers of ACRMs. A certifier of chemical and biological quantities must have the technical competence to verify that declared values are sound, which can be evidenced by appropriate NATA accreditation. NATA accredits reference material producers under ISO 17034.

Example of an ACRM in practice:

Enforcement of drink driving legislation relies on the effective calibration of Evidential Breath Analysers. Ethanol solution ACRMs are produced by NMI and these are issued with Regulation 48 Certificates under the Act to provide legal certainty as to the traceability of the reference values.

Confidence in traceable measurement of chemical and biological quantities is also supported by the broader standards and conformance infrastructure. The general NATA approach to the recognition of the traceability of CRMs is that they should come from a national metrology institute or be from an accredited CRM producer. Appropriate foreign CRMs are also recognised by NATA in regard to the accreditation of laboratories compliant with ISO 17034; whereas, under the Act, foreign CRMs are not automatically recognised.

When there is no CRM available, NATA's suggested framework is based on the approach provided by *ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories* with guidance provided in NATA's General Accreditation Criteria (GAC) Metrological Traceability. Under this framework, in the absence of a CRM, NATA allows for the use of other materials that are fit for purpose.

35 Reference materials become certified as Australian certified reference materials under regulation 48 of the NMR.

36 Paragraph 18(2) (b) of the Act specifies one of the Commonwealth's metrological functions as being that of "*realising units of measurement through the development and maintenance of standards of measurement, reference materials and reference techniques*."

37 Refer to NMR Part 5 (Reference materials) regulation 53: Recognition of foreign reference materials.

5.2 Issues and questions

5.2.1. Certified Reference Materials (CRMs) and Australian Certified Reference Materials (ACRM)

CRMs may be legally recognised under the legislation in order to become ACRMs.[38] This enables the measurement of ACRMs to be defensible in Australian courts of law using a Regulation 48 certificate under the Act. Most users of CRMs are not aware of the terminology used in the Act or of the existence of ACRMs.

QUESTIONS

5.2.1.a. Does a CRM, which has been certified but not in accordance with the legislation, need to be included within the measurement framework? If so, when should it be recognised under the Act?

5.2.1.b. What risks or benefits do you see in having ACRMs operate under the Act (and be capable of being used for both scientific and legal purposes) while having CRMs operate outside the Act?

5.2.1.c. Have you had any experience with deciding whether or not to seek certification of a reference material as an ACRM? If so, what were the factors which influenced whether the decision made was to seek certification or not?

5.2.1.d. Do you see value in changing the framework for ACRMs? If so, how and why?

5.2.1.e. Should the Act's recognition of CRMs more closely align with NATA's approach? Why?

5.2.1.f. How efficient and effective would it be if Regulation 48 certificates under the Act more closely aligned with the ISO Guide 31:2015 'Reference Materials-contents of certificates, labels and accompanying documentation'?

5.2.2. Mechanisms of legal assurance for chemical and biological measurement systems

Laboratory accreditation is a formal process for assuring that those laboratories are competent and able to perform to defined standards. The Act recognises accreditation by NATA as an option for recognising capabilities for the appointment of verifying and certifying authorities. However, cutting-edge chemical and biological measurements often lack certified reference materials and accreditation may not be available.

QUESTIONS

5.2.2.a. In what ways could the Act be amended to enable and support traceability relating to chemical and biological quantities? What would the benefit be? What would the costs be?

5.2.2.b. Should the legislation focus more strongly on providing legal assurance of the accuracy of the results of chemical and biological measurements through an accreditation-based framework? If so, how and why?

5.2.2.c. In what circumstances does testing fall outside the framework of NATA accreditation processes?

5.2.2.d. How could the legislation deal with new areas where the underpinning accreditation framework is not yet settled? For example, scientific advancements in chemical and biological measurements may take time for appropriate reference materials and reference methods to be developed.

38 The Act Section 3 definition: "*Australian certified reference material means a reference material that has been certified in accordance with the regulations and for which the certification is in effect.*" This definition refers to regulation 48 of the NMR (Certification of reference materials).

5.2.3. International certified reference materials

The appropriate CRM may not be available in Australia, for example, due to bio-security hazard constraints. Although the Act only recognises ACRMs, these can include foreign CRMs that have been recognised by the Chief Metrologist as ACRMs[39]. The need for additional recognition under the Act of international CRMs may be interpreted as a burden or market barrier.

QUESTION

5.2.3.a. Have you had any experience with deciding whether or not to seek recognition of an overseas CRM under the Act? If so, what were the factors which influenced whether the decision made was to seek recognition or not?

5.2.4. General matters

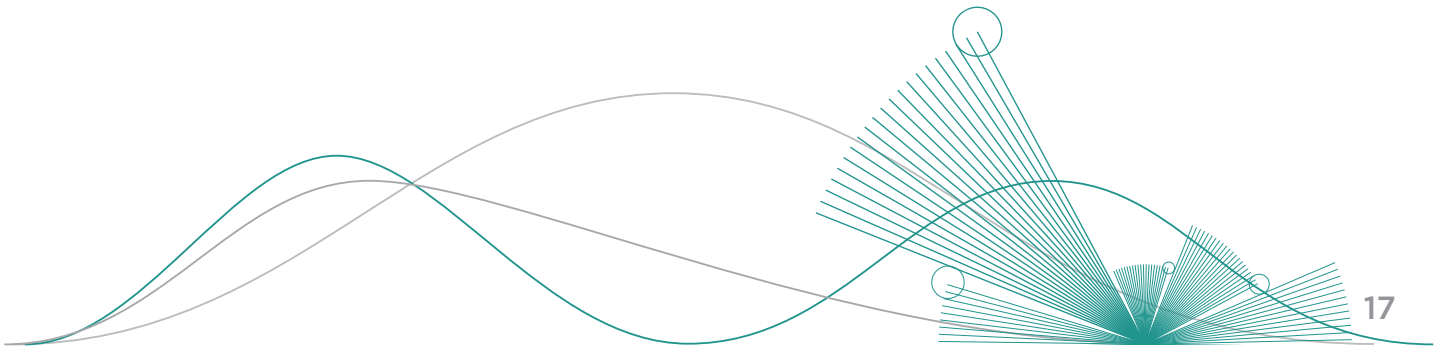
QUESTIONS

5.2.4.a. In what additional ways could the Act be amended to support and enable traceability relating to chemical and biological quantities?

5.2.4.b. What costs are incurred by your business as a result of the current arrangements?

5.2.4.c. How could current arrangements be made more efficient?

39 Refer to NMR Regulation 53 (Recognition of foreign reference materials).



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