Summary of Submissions from Discussion Papers 2 to 4

Measurement Law Review
2019

Contents

SUMMARY PAPER:
MEASUREMENT IN
EVERYDAY LIFE

MEASUREMENT LAW REVIEW – DISCUSSION PAPERS

1 Scope of Australia's Measurement Laws
2 Traceable Measurement
3 Measuring Instruments
4 Measurement-based Transactions
5 Third Party Arrangements
6 Compliance Arrangements

1. Background

The Measurement Law Review (Review) is identifying aspects of Australia's measurement framework that can be modernised, streamlined or simplified. The Review includes public consultation on six discussion papers to gather input and provide industry and key stakeholders with the opportunity to inform the Review.

This document provides a summary of the various submissions received during the public consultation ***Measurement in Everyday Life*** open from 4 April to 23 June 2019. The summary covers both confidential and non-confidential submissions from all three discussion papers:

- ***Traceable Measurement***
- ***Measuring Instruments***
- ***Measurement-Based Transactions***

The submissions summarised in this document provide a range of different views, some of which are competing positions. The Review will consider the different perspectives provided during consultations when developing options for reform. Further consultation will be undertaken on these options once developed.

2. Paper 2 – Traceable Measurement

Comments received on the Traceable Measurement discussion paper indicated:

2.1 The Legal Framework

2.1.1 Section 10 of the *National Measurement Act 1960* is effective and plays an important role in underpinning measurement traceability but:

a. Is complex to understand for those unfamiliar with measurement law; and

b. Traceability can still be compromised. Although section 10 is aligned to very specific references, the Act is silent on processes that facilitate the linkages in traceability or the basis of performance, which could be compromised in many ways in the laboratory, e.g. through methodologies or control of quantities.

2.1.2 There are no known alternative frameworks to the current traceability pathways that determine whether a measurement of a quantity is being made correctly with reference to an Australian Legal Unit of Measurement (ALUM), and no alternatives should be allowed. The Australian standards framework is used within state level legislation in relation to accuracy of devices but not in reference to an ALUM, which is not specified in state level legislation. Refer to the section on chemical and biological quantities for recommendations of how the traceability for chemical and biological quantities could be strengthened using international frameworks that currently exist.

2.1.3 The Australian government could make traceability assurance mechanisms more accessible for non-trade purposes. Some benefits cited in submissions include: broadening the technologies that are accepted as suitable; ensuring standards and related processes are relevant/current; protecting public safety and wellbeing; ensuring environmental monitoring values are accompanied by uncertainty values; and new technologies increase efficiencies including delivering value for money. The willingness to adopt traceability assurance will depend on the risk from unsatisfactory measurement results in sectors such as maritime, health, safety and medical.

2.1.4 There is a reliance on integrity of measurement, even without interacting with the National Measurement Institute (NMI). While there are facilities that do not work within the measurement framework and are not using measurement for a legal purpose, these facilities nevertheless work with regulation and are concerned with confidence of results.

2.2 Traceability of Physical Quantities

2.2.1 Some respondents consider the measurement framework has the right balance and is not onerous. Although the framework is prescriptive it provides reference and traceability. However, some consider the National Instrument Test Procedures (NITPs) are the element of the framework that is currently too prescriptive. It was further suggested to review the application processes, documents and forms used for regulation 12, 36, 37 and 46 of the National Measurement Regulations 1999.

2.2.2 Greater flexibility could be considered within the pattern approval process when introducing new technology, enabling testing procedures to be developed in conjunction with manufacturers.

2.2.3 A wholly principles-based approach was not necessarily viewed as suitable or practical for the measurement framework. Respondents identified this approach creates uncertainty which is opposed to the rigor of metrology. For example, weighing is absolute and requires definitive results to maintain integrity and confidence. In applying a principles-based approach to parts of the framework, due consideration should be provided to any information imbalance between supplier and user in that area. The approach should be informed through consultation and collaboration with stakeholders. The principles would need to be incorporated into Commonwealth and state legislation.

2.2.4 A range of legal assurances to provide confidence in self-calibrating devices could include: mandatory testing periods; a test/rate regime under NMI; pattern approval; penalties if found substandard; periodic calibration; and a certification process.

2.2.5 All respondents consider in-built references for self-verifying instruments should be traceable when used for trade and also for any other legal purposes, and that these references should undergo calibration and be re-verified. Submissions indicated it is very important to know whether manufacturer's claims of self-calibrating devices are supported by the measurement framework. As such, the government's role in assuring traceability of built-in references to self-calibrating instruments should include pattern approval and conformity to type compliance.

2.2.6 The current standards and conformance infrastructure meets the traceability needs of respondents where the measurement infrastructure exists. There is concern about the security, authenticity and integrity of measurement results associated with new technologies and their source of traceability, unless the user relies on accreditation and use of technologies that have gone through validation processes.

2.2.7 The measurement framework does not easily enable new technologies to be explored. It was proposed the measurement framework could support confidence in measurements based on new and advanced technologies through pattern approval, liaising with industry, and investigating the validity of methods and devices that are proposed to achieve traceability. It was recognised a challenge to gain clarity about how the introduction of new technologies interact with the measurement framework and how to resolve disputes when measurements are based on overseas standards.

2.2.8 There are additional ways the legislation could support traceability. Mandatory reverification periods may better enable verification or certification to deliver on assuring traceability and confidence in measurement results in the long term. Strengthening the legal standing of certificates of standards of measurement to reduce legal challenges would also support this. Another suggestion proposed was for an electronic system of verification, using a unique identification code for devices with their history in a database. Further suggestions include: to legislate for greater international equivalence with overseas regulations, increase the awareness among Australian businesses of Australian testing capability and its international recognition (e.g. labelling equivalence to overseas trading partners), and give more powers for the Chief Metrologist to recognise appropriate overseas expertise.

2.2.9 While some industries considered they do not face any traceability problems, other industries consider there is insufficient evidence of traceability.

2.2.10 Traceability could be enhanced by strengthening measurement legislation to prevent challenges to certificates and at the same time recognise calibration certificates issued by accredited laboratories that can show traceability. Clarity is needed on how new technologies interact with the measurement framework and how to resolve measurement-based disputes.

2.2.11 Industry incurs considerable investment cost to meet the requirements of the framework, and current arrangements could be more efficient. Suggestions for how this could occur included: mandatory reverification periods, electronic monitoring, clarifying traceability requirements for test equipment and reference equipment versus working equipment, simplifying the language in the legislation, and alignment of advice received from both National Association of Testing Authorities Australia (NATA) and NMI.

2.3 Traceability of Chemical and Biological Quantities

2.3.1 The legislation currently provides legal standing for some certified reference materials (CRMs) e.g. for law enforcement purposes and allows CRMs to be recognised in Australia given conditions for certification e.g. their traceability. While recognition of CRMs under the Act is used for legal purposes, legal standing of CRMs are not generally needed in other areas. However, there is potentially value in providing legal standing to some other CRMs in legislation:

a. The legislation could recognise internationally accepted CRMs where they are in an international database of high order CRMs (**JCTLM**[1]), comply with ISO 15194 and are subject to quality assurance.

b. The legislation could include a legal definition of CRM to help guide understanding of what is a CRM and distinguish the difference between high order CRMs and those that are not.

c. The framework could indicate that CRMs should be produced to ISO 17034, and distinguish high accuracy CRMs from standard reference materials. This would support areas that depend on highly accurate CRMs (e.g. proficiency testing) and highly accurate results required for clinical tests that determine cut-points with certainty e.g. is the patient a diabetic? to determine when a person is infected, when a person starts treatment and assess whether it is effective treatment.

d. The following were suggested as potentially needing some legal standing: interlocks used in cars,[2] liquefied natural gas (LNG) CRM at custody transfer, CRMs used for emissions testing, drugs, steroids, and where used as evidence in court.

1 Joint Committee for Traceability in Laboratory Medicine. See https://www.bipm.org/en/committees/jc/jctlm/

2 An alcohol ignition interlock is a breath test device linked to the ignition system of a vehicle. For more information see: https://www.qld.gov.au/transport/safety/road-safety/drink-driving/interlocks

2.3.2 Having Australian Certified Reference Materials (ACRMs) operate under the Act provides confidence and traceability to a known quantity that is understandable to all. Having CRMs outside the Act enables a change in the cost, an increased number of suppliers and consequently increased competition. The risks posed by the current two-fold arrangement are:

a. it leaves room for confusion, misunderstanding and misinterpretation by the public and judicial system regarding the differences between ACRMs and CRMs (in a legal context);
b. changes in the quality and confidence of the CRM when compared with the ACRM;
c. wide variability in quality can occur depending on the source of the CRM;
d. wrong understanding of what a CRM is; and
e. wrong use of CRMs occurs.

2.3.3 Seeking certification gives significant weight in legal challenges or in matters of highest priority. Those that do not seek certification noted they depend on accreditation to relevant international standards and peer reviews or assessments.

2.3.4 Respondents from one sector were of the view that there is value in changing the framework for ACRMs to increase supply and competition. Some suggested changes include: recognise foreign CRMs to promote increased supply options/competition, and recognise accreditation to ISO/IEC 17025, ISO 15194 and ISO 17034 as a parallel to ACRMs used as evidence at court.

2.3.5 Current arrangements could be made more efficient by establishing an approved supplier list for ACRMs, investigating a Memorandum of Understanding (MOU) to supply ACRMs to all police jurisdictions, or increasing ACRM suppliers by recognising NATA accredited laboratories.

2.3.6 There are diverging views about aligning the Act's recognition of CRMs more closely with NATA's approach. While doing so might provide confidence in the validity of measurement and enhance professional recognition of CRMs, it may also cause confusion. Another submitter recommended that the recognition of the CRM in the Act should align with the relevant international (ISO 15194[3]) standard for the quality assurance process.

2.3.7 Traceability of chemical and biological quantities could be supported by:

a. Strengthening legal recognition of the test certificate issued by an accredited laboratory.
b. Having traceability and participation in traceability programs written into law.
c. Recognition of international standards in measurement legislation.
d. Reducing information asymmetry. Laboratories achieve traceability through calibrators provided by manufacturers albeit some steps away from primary reference standards. Information provided by manufacturers should be more comprehensive (e.g. how they make assays traceable); and calibrations and values need to be investigated. More transparency is required to support traceability.

2.3.8 Greater recognition of calibration certificates and reports would provide legal assurance for chemical and biological quantities. There was a lot of support for providing assurance through the accreditation based framework and other mechanisms.

a. The legislation could recognise accreditation status and compliance to specific ISO standards as a source of assurance, when considering recognising specific CRMs for legal standing within Australia. Legal assurance could be considered for specific areas as required.
b. Legislation could include participation in traceability programs as a form of assurance. This can be particularly important in areas where accurate measurement is essential.
c. Scrutinising information provided by manufacturers for correctness and completeness.
d. Providing greater weight or recognition to Calibration Certificates (or Calibration Reports), to eliminate the need for a regulation 48 certificate, would deliver benefits to customers.

2.3.9 Alternative methods can be utilised when reference material and methods have been validated and determined to be traceable. Such methods are considered on a case-by-case basis. Testing activities that fall outside the Act are also outside the NATA framework. In these cases, laboratories seek other laboratories to compare their testing results or seek overseas sources.

3 ISO 15194:2009 In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation

2.3.10 Certificates issued under regulation 13, 37 and 48 of the *National Measurement Regulations 1999* could be made more defensible to reduce the occurrence of legal challenges to traceability.

2.3.11 In dealing with new areas, alternative methods demonstrating traceability can be utilised when reference material and methods have been validated and determined to be traceable. These alternative methods are considered in a case-by-case basis or as per ISO/IEC 17025:2018. Emerging areas are a concern, noting that as adoption of technology increases, variability is increasing and reliability is decreasing. Confidence could be provided as part of the certificate of analysis, which would be supported by external quality assurance mechanisms. One desirable mechanism is for NMI to provide a target value to compare with, thus giving a basis for confidence.

2.3.12 While law enforcement agencies seek legal standing under the Act for overseas CRMs they use, other respondents that use overseas CRMs do not require them to have legal recognition under the Act.

a. One respondent stated that an alternative international supplier would be considered if the cost of domestic supply was not able to deliver value for money.

b. Another respondent stated that it would be useful to recognise high order CRMs from overseas, so that the NMI does not duplicate efforts of international measuring institutes and can specialise in specific areas of competitive advantage.

c. Another respondent confirmed that in their area of activity, legal traceability is generally not that essential although it aids the accuracy of research work. Where CRMs are obtained from overseas, one respondent indicated they source CRMs from internationally trusted sources that claim to have traceability and provide enough information on their certificates, e.g. uncertainty quoted against each value.

2.3.13 Traceability relating to chemical and biological quantities could be supported and enabled in the following ways:

a. A legislated definition of a CRM to remove confusion as to what a CRM is. Providing clarity around the requirements for what a CRM is and its use in applications would be an improvement to the framework. This is also important because there can be a legal dispute if someone knowingly uses a material that does not have the required certification. The definition needs to be clear and understood. It is not sufficient that a CRM carry a certificate from a laboratory accredited by NATA only to ISO 17025.

b. Facilitate values for critical materials used for some pathology tests.[4]

c. Information provided by manufacturers should include comparisons against high accuracy CRMs produced by reliable sources.

d. Information provided by instrument manufacturers to include traceability linked to international reference standards and calibrations used.

e. Laboratory internal quality controls to ensure accuracy and reliability of instruments. Users should not just rely on information from manufacturers. Users need regular (daily, monthly, periodic) calibration of their instruments against traceable standards to ensure traceability of measurement results provided by the instruments.

2.3.14 Costs incurred by businesses within the measurement framework are linked to the cost of purchasing ACRMs relevant for legal purposes. For those operating outside the framework, costs are linked to the purchase of high accuracy CRMs whether domestically or internationally.

2.3.15 Current arrangements could be made more efficient by:

a. having an NMI approved supplier list for ACRMs and increasing ACRM suppliers by recognising NATA accredited laboratories that could produce these materials;

b. a Memorandum of Understanding (MOU) to supply ACRMs to police jurisdictions;

c. recognition of international standards; or

d. including a definition of a CRM and distinguish (a) high order CRMs from (b) other standard reference materials.

4 Some examples of critical materials are: 1) creatinine for chronic kidney failure; 2) cholesterol as a risk factor for cardiac disease; 3) HbA1c for diabetes diagnosis and monitoring; and 4) testosterone for patients wishing to access androgen replacement therapy.

3. Paper 3 – Measuring Instruments

Comments received on the Measuring Instruments discussion paper indicated:

3.1 Measuring Instruments – Current Approach

3.1.1 Many respondents identify pattern approval as a cost while acknowledging a service charge was reasonable. Although responses indicated substantial investment was required, they understood that it was necessary and the benefits for a strong and confident trade measurement system justified the investment.

3.1.2 Respondents generally support existing arrangements for measuring instruments, particularly with respect to the verification and certification frameworks for trade and legal measuring instruments, indicating the cost for certification was reasonable.

3.1.3 The level of certainty provided (for trade and legal requirements) and providing a 'level playing field' for industry are key benefits of the current framework.

3.1.4 Some respondents consider the measurement legislation should be extended to include high-risk non-trade instruments within its scope, such as those used in relation to health, safety, tax collection and law enforcement.

3.1.5 The current system appears to strike a good balance between the interests of the different entities involved but could benefit from reducing prescription.

3.1.6 Review of existing exemptions of non-urban water meters may be necessary. This is on the basis that this exemption along with the costs of pattern approval and the lack of mandatory pattern approval requirements by state jurisdictions has contributed to the slow pace of pattern approvals and consequent availability of pattern approved meters on market. The exemption was useful when it was introduced to allow for a transition but it is not necessary anymore and is now a hindrance to sector development.

3.1.7 A respondent expressed concerns about the testing under Australian metering standards, indicating that it does not accurately represent energy use of modern appliances.

3.2 Measuring Instruments – Reliability

3.2.1 Accurate measurement is important across the energy supply chain and accurate metering provides consumers with confidence in the usage charges they are billed for. Several issues were raised in submissions including: possible inaccuracy of current transformer testing methods and the extension of the regulatory framework to cover transformers. These will be explored further with the electricity industry.

3.3 Measuring Instruments – Flexibility

3.3.1 Flexibility with respect to new technology is important. There were suggestions supporting the development of a process for implementation of new technology, including a testing regime that compares new technology with existing instruments.

3.3.2 New technologies are a major challenge to regulate in the medical sector, noting the proliferation of wearable medical gadgets, and remotely calibrated and programmed medical equipment. One respondent submitted that for most non-prescription medical devices and products, quality is assessed on a principles-based framework focused mainly on the reduction of risk and harm minimisation (risk avoidance mechanism).

3.3.3 Verification requirements could contain more flexibility to allow licensees and manufacturers to develop their own test procedure for review in certain circumstances (where for example no current NITP process exists).

3.4 Approval for Use – Pattern Approval

3.4.1 The cost of NMI pattern approvals appears reasonable but the process and duration for approvals could be improved and be more efficient.

3.5 Ongoing Confidence – Verification

3.5.1 At least one industry supports the introduction of mandatory reverification periods. However, none of the submitters provided any data or other evidence to back up their support for introducing reverification periods. A respondent in the petroleum industry suggested reverification of retail equipment should be every two/three years suggesting that some equipment in the industry may not meet standards.

3.5.2 The current framework provides for community confidence, transaction integrity and meets respondents' needs. One submitter suggested the framework would benefit from including a number of areas into the regulatory system for measurement that are currently exempt like pressure, time and emissions.

3.5.3 Respondents consider verification and certification to be an effective and efficient means of ensuring and demonstrating accuracy for the purposes to which they are applied. No data was provided to assess the cost-benefit for implementing such changes.

3.5.4 Certain methodologies applied in the electricity sector may produce inaccuracies in measurement and affect traceability, and consideration should be given to extending the regulatory framework to transformers. These issues are being followed up with industry stakeholders and engagement with the Commonwealth regulator.

3.6 Ongoing Confidence – National Instrument Test Procedure (NITP)

3.6.1 There is some concern that meter verifiers are mainly the product manufacturers or traders who only hold their appointment as a Legal Metrology Authority to test their own instruments. Other market operators are charged high fees to test instruments, which has an impact on prices and creates a monopoly. The submission also queried NMI's policy to only accept local Australian labs as Utility Meter Verifiers which extends the market monopoly and high verification fees. The submitter proposed NITP 14 fees costs be regulated or NMI should accept test results from overseas accredited labs.

3.6.2 Introducing alternate pathways for pattern approval for new and emerging technologies should be considered where the requirement to test an instrument against an NITP may present challenges if an NITP does not exist to verify the measuring device.

3.7 Ongoing Confidence – Pattern Compliance

3.7.1 A number of respondents have found that although pattern approval has been effective there have been delays in receiving approval for equipment due to the lack of resources at NMI.

4. Paper 4 – Measurement-Based Transactions

Comments received on the Measurement-based Transactions discussion paper indicated:

4.1 The Current Framework for Measurement-based Transactions

4.1.1 The framework provides protection to consumers and businesses. There was no suggestion the regulation of measurement-based transactions was inappropriate.

4.1.2 There is a lack of flexibility and international harmonisation in a variety of areas including packaging requirements, determination of how products can be sold (e.g. by weight or by number) and requirements relating to glassware.

4.1.3 There is a need for regulations to ensure consumers have access to consistent and comparable information and that requirements are clear and specific to provide a level of certainty and confidence to small business.

4.1.4 Any changes made should focus on improving ease of use so the law is easy to understand and implement.

4.1.5 Some areas currently exempt under the legislation require further assessment to determine whether exemptions are still appropriate. These include: utility (electricity) measurements, data usage and extension of verification requirements to include high-risk non-trade applications (e.g. health, medical safety, tax collection and litigation).

4.2 Incorrect Measurement (Shortfall)

4.2.1 There is a support for offences to be included in the legislation relating to incorrect measurement. This included expansion beyond the current offences that relate only to the sale of goods.

4.2.2 There should be flexibility in offences for incorrect measurement. Specific defences could be included where the business can demonstrate that appropriate processes were followed and steps taken to ensure instruments are accurate.

4.2.3 Some tensions exist in the current framework between flexibility and accuracy/reliability of measurement, especially in relation to the incorporation of sustainable packaging and purchases.

4.2.4 Avoid duplication with other state and federal legislation where practicable, follow best practice regulatory principles and ensure measurement laws and other relevant laws (e.g. the Grocery Unit Pricing Code) remain complementary and provide an easy-to-use comprehensive system.

4.3 Goods Sold by Reference to Measurement

4.3.1 It is appropriate for legislation to prescribe how certain goods should be sold, however there needs to be more flexibility in the system.

4.3.2 Tensions are apparent between the position taken by industry for increased flexibility and harmonisation and those of consumer groups who support the retention of requirements that certain goods be sold in a prescribed manner.

4.3.3 Further analysis is required regarding the prescription of requirements relating to the sale of alcohol. There is some support for deregulation of current requirements as well as support for the expansion of regulatory requirements in this area.

4.3.4 There is support for the continuation of mandatory requirements for a measurement to be marked on packaged goods. Respondent's positions differed in relation to the level of prescriptiveness regarding where and how the measurement marking is applied.

4.4 Testing Packaged Goods

4.4.1 The current approach to testing packaged goods is appropriate and there is support for continuing to recognise the two current systems for determining the measurement of packaged goods. This supports flexibility for large and small business, as well as products imported from various countries.

4.4.2 Further analysis is required regarding the suggested introduction of requirements for trade approved check-weighers.

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