REPLACEMENT EXPLANATORY STATEMENT

Issued by the authority of the Chief Metrologist

National Measurement Regulations 1999

National Measurement (Australian Certified Reference Materials)

Determination 2023

Purpose and Operation

The National Measurement (Australian Certified Reference Materials)

Determination 2023 (the Determination) sets requirements for determining the properties of reference materials, which are used in the measurement of property values of other materials and the calibration of certain types of measuring instruments. Its purpose is to provide consistency in the manner and methods by which the property values of any kind of Australian certified reference material are established under the National Measurement Regulations 1999 (the Regulations), made under the National Measurement Act 1960 (the Act).

Maintaining a consistent approach in the manner and methods by which the property values of any kind of Australian certified reference material are established provides support for the comparison of different measurements and allows for an assessment of the accuracy of measurements across the national measurement system. In other words, this approach supports the use of Australian certified reference materials and the propagation of units of measurement throughout the Australian economy; in turn providing confidence in the accuracy of measurement results used for trade transactions and other legal purposes.

The Determination requires that the uncertainty of the property values of Australian certified reference materials are established in accordance with international standards and are consistent with methods for ascertaining other physical quantities under the Act.

Background

The objects of the Act include to:

- establish a national system of units and standards of measurement of physical quantities;
- provide for the uniform use of those uniform units and standards of measurement throughout Australia;
- co-ordinate the operation of the national system of measurement; and
- provide the legal framework for a national system of trade measurement.

The Regulations allow for the Chief Metrologist to determine the manner, methods or characteristics by which the property values of reference materials of a stated kind must be established for certification for the Regulations.

The Determination requires compliance with the principles of various international standards. Some of these standards are only available for a fee. These standards are essential for the international harmonisation of requirements and practice in the

measurement of property values of reference materials. There are no freely available alternatives.

Details of the Determination are set out in **Attachment A**.

The Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Authority

The Determination is made under subregulation 52(1)(a) of the Regulations. Under paragraph 52(1) of the Regulations, the Chief Metrologist may determine:

- a) the manner, methods or characteristics by which the property values of reference materials of a stated kind must be established for certification for the Regulations; and
- b) a matter about a particular reference material, or reference materials of a particular kind, that is relevant to the proper use of the material or materials that must be stated in a certificate under paragraph 55(j) of the Regulations.

Consultation

The Determination supports the work of Certifying Authorities that are appointed under the Regulations. The National Measurement Institute consulted with all appointed Certifying Authorities regarding the Determination during the period 5 June 2023 to 7 July 2023.

All feedback received from Certifying Authorities agreed with the contents of the Determination and supported the alignment with relevant international standards.

Regulatory Impact

The Office of Impact Analysis (OIA) was consulted concerning the development of the Determination. OIA advised that the Determination was likely to have only a minor regulatory impact. As such, the preparation of a formal Impact Analysis was not required.

A Statement of Compatibility with Human Rights is at **Attachment B**.

<u>Details of the National Measurement (Australian Certified Reference Materials)</u> Determination 2023

Clause 1 – Name

This clause specifies the name of the Determination is the *National Measurement* (Australian Certified Reference Materials) Determination 2023.

Clause 2 – Commencement

This clause provides that the Determination will commence the day after registration on the Federal Register of Legislation.

Clause 3 – Authority

This clause provides that the Determination is made under the *National Measurement Regulations 1999* (the Regulations).

Clause 4 – Definitions

This clause provides for definitions of terms used in the Determination.

Clause 6 – Determination

This clause details the determinations of the Chief Metrologist, concerning Australian certified reference materials.

Subclause 6(1) requires that the accuracy of property values of Australian certified reference materials be ascertained and expressed as an uncertainty in accordance with the principles of the JCGM 100:2008 – Evaluation of measurement data – Guide to the expression of uncertainty in measurement. The use of the JCGM 100:2008 guide provides for a consistent approach to the quantification and expression of the measurement uncertainty of property values of Australian certified reference materials and aligns with internationally accepted best practice.

Subclause 6(2) requires that measurements which establish the property values of any kind of Australian certified reference material comply with section 10 of the Act. Section 10 of the Act provides a framework for demonstrating legal traceability, to the Australian legal units of measurement (ALUMs), for measurements of a quantity made for legal purposes.

The Determination clarifies the application of section 10 of the Act in this case; that the measurement of property values of Australian certified reference materials are measurements made for a legal purpose, and that it is necessary that those measurements are ascertained in terms of ALUMs. As Australian certified reference materials are listed under section 10 as a means of demonstrating legal traceability, it stands to reason that the measurements that establish the property values of Australian certified reference materials must also be legally traceable.

Subclause 6(3) requires the manner and methods by which the property values of any kind of Australian certified reference material are established shall be in accordance with the principles of ISO/IEC 17025, ISO 17034, and ISO Guide 35. Compliance with the principles of these international standards will support confidence and trust in the production and certification of Australian certified reference materials.

Additional information as well as the location of the international standards is provided as follows:

- *JCGM* 100:2008 Evaluation of measurement data Guide to the expression of uncertainty in measurement (JCGM 100:2008) represents international best practice with respect to the ascertainment and expression of measurement uncertainty. JCGM 100:2008 is available here: https://www.bipm.org/en/committees/jc/jcgm/publications
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017) specifies the general requirements for the competence, impartiality and consistent operation of laboratories. The international standard provides a means by which the competency of a laboratory may be demonstrated and recognised via third-party accreditation or assessment.
- ISO 17034:2016 General requirements for the competence of reference material producers (ISO 17034:2016) specifies general requirements for the competence and consistent operation of reference material producers. ISO 17034:2016 sets out the requirements in accordance with which reference materials are produced. It is intended to be used as part of the general quality assurance procedures of the reference material producer and covers the production of all reference materials, including certified reference materials.
- ISO Guide 35:2017 Reference materials Guidance for characterization and assessment of homogeneity and stability (ISO Guide 35:2017) explains concepts and provides approaches to the following aspects of the production of reference materials the assessment of homogeneity:
 - the assessment of stability and the management of the risks associated with possible stability issues related to the properties of interest;
 - the characterization and value assignment of properties of a reference material;
 - the evaluation of uncertainty for certified values; and
 - the establishment of the metrological traceability of certified property values.

The above international standards are incorporated by reference at the date of commencement of the Determination.

The guidance given in ISO Guide 35:2017 supports the implementation of ISO 17034:2016. ISO/IEC 17025:2017, ISO 17034:2016 and ISO Guide 35:2017 are available here: https://www.iso.org/store.html

ATTACHMENT B

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny)

Act 2011

National Measurement (Australian Certified Reference Materials) Determination 2023

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The National Measurement (Australian Certified Reference Materials) Determination 2023 (the Legislative Instrument) supports the national measurement system by providing consistency and trust in the production and certification of Australian certified reference materials under the National Measurement Regulations 1999.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

The Chief Metrologist

Dr Richard Bruce Warrington