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Department of Industry,  
Science and Resources

National  
Measurement  
Institute

# NMI R 126:2025

# Evidential breath analysers

Guide to pattern approval and certification

National Measurement Institute | March 2026

Measurement for a fair, safe, healthy  
and competitive Australia

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# 1 Introduction

This document provides information and guidance on parts of the metrological control system for evidential breath alcohol analysers, also known as evidential breath analysers (EBAs), in Australia. It provides information regarding the adoption of the OIML Recommendation, OIML R 126:2021 *Evidential breath analysers*, its publication and implementation in Australia as NMI R 126:2025 *Evidential breath analysers*. It explains the key differences between those documents. It also provides guidance on the roles and responsibilities of participants within the system.

## 1.1 International context

The International Organization of Legal Metrology (OIML) is an international treaty organisation. It is responsible for the development of harmonised requirements (published as OIML Recommendations) intended for the regulatory control of measuring instruments. As a signatory to the OIML Treaty, Australia is morally obliged to adopt and implement OIML Recommendations, such as OIML R 126, in Australia as national pattern approval requirements.

## 1.2 Metrological control systems

A metrological control system incorporates physical infrastructure and documented requirements intended to provide confidence in the use of measuring systems for legal purposes. The metrological control system for EBAs in Australia includes, but is not limited to, the following parts:

- a) measurement legislation to support the approval, testing and use of EBAs
- b) the Chief Metrologist and the National Measurement Institute (NMI)
- c) approving authorities and certifying authorities
- d) traceable standards: reference standards of measurement, certified measuring instruments and Australian certified reference materials
- e) pattern approval requirements specified in NMI R 126
- f) NATA accreditation and competency requirements
- g) laboratory and field-testing capability and supporting procedures.

## 1.3 National measurement legislation and NMI

NMI, a division of the Australian Government Department of Industry, Science and Resources is responsible for administering Australia's national measurement laws and regulations, which include the:

- a) *National Measurement Act 1960* (Cth)
- b) *National Measurement Regulations 1999* (Cth)
- c) *National Trade Measurement Regulations 2009* (Cth)
- d) *National Measurement Guidelines 2016* (Cth).

The Act and Regulations establish a framework for the pattern approval and certification of measuring instruments used for legal purposes (other than trade), such as EBAs. However, the Act and Regulations do not mandate that measuring instruments used for legal purposes (other than trade) be pattern approved and certified.

NMI works in partnership with other agencies to provide for the pattern approval and certification of legal measuring instruments in support of state and territory regulations and requirements.

NMI is also responsible for supporting the Chief Metrologist in the performance of their functions and duties under the national measurement legislation.

## 1.4 Pattern approval requirements for EBAs

Australia's pattern approval requirements for EBAs are specified in NMI R 126:2025, which is adopted from OIML R 126 and published in 3 parts as:

- a) NMI R 126-1:2025 *Evidential breath analysers Part 1: Metrological and technical requirements*
- b) NMI R 126-2:2025 *Evidential breath analysers Part 2: Metrological controls and performance tests*
- c) NMI R 126-3:2025 *Evidential breath analysers Part 3: Test report format*

The above documents are available on the [Pattern approval requirements page](#) of the Department of Industry website.

The transition timeframe for the implementation of NMI R 126:2025 to replace NMI R 126:2013 is provided below in clause 3.5 and specified in NMI R 126:2025.

## 2 Explanation of key terms

OIML's system of documentation and Australia's metrological control system have some differences in terminology. These differences are a result of the different historical evolution of terms and definitions in the Australian and international communities, and OIML specifically. There are ongoing efforts to align terminology between the 2 systems, but it is not always possible because the systems are complex.

The explanations in this section will help you interpret and apply the Australian pattern approval requirements document NMI R 126:2025 as based on OIML R 126:2021.

### 2.1 Type and pattern

In OIML documentation, 'type' is the design of a measuring instrument as it relates to its measurement operation and performance. Type evaluation concerns the conformity assessment procedure on one or more specimens of the identified type. Type approval is the regulatory decision to approve an identified type of measuring instrument.

In Australia, we use the term 'pattern'. It has the same meaning as 'type'. The processes of 'pattern evaluation' and 'pattern approval' are the same processes as 'type evaluation' and 'type approval'.

In NMI R 126:2025 the term 'type' is equivalent to and taken to mean 'pattern' under the *National Measurement Act 1960* (Cth).

### 2.2 Verification and certification

OIML R 126 uses the term 'verification' to describe a conformity assessment procedure (other than pattern evaluation), which results in the affixing of a verification mark and/or issuing of a verification certificate. This process typically involves testing and examining a measuring instrument in accordance with a defined procedure to ensure that it is:

- operating within maximum permissible errors
- of an approved pattern.

In Australia, measuring instruments used for trade may be verified; measuring instruments used for other legal purposes may be certified. As such, EBAs may be certified as certified measuring instruments in accordance with regulation 37 of the National Measurement Regulations 1999 (Cth).

In NMI R 126, the term 'verification' is equivalent to and taken to mean 'certification' under the National Measurement Regulations 1999 (Cth).

### 2.3 National authorities

OIML R 126 uses the term 'national authorities' to describe persons and organisations responsible for the control of measuring instruments in a jurisdiction.

Australia's national authorities are listed below. They are empowered to perform the functions described in relation to the testing, pattern evaluation, pattern approval and certification of EBAs.

#### 2.3.1 The Chief Metrologist

The Chief Metrologist is responsible for testing, pattern evaluation, pattern approval and certification of EBAs. The Chief Metrologist also appoints approving authorities and certifying authorities.

## 2.3.2 Approving authorities

Approving authorities are appointed by the Chief Metrologist to perform testing and pattern evaluation for EBAs. The testing and evaluation performed by an approving authority may be submitted to the Chief Metrologist to inform their decision about the approval of a pattern of EBA.

## 2.3.3 Certifying authorities

Certifying authorities are appointed by the Chief Metrologist to perform testing and certification for EBAs. Certifying authorities may certify EBAs as certified measuring instruments under Regulation 37 of the National Measurement Regulations 1999 (Cth).

## 2.3.4 The National Evidential Breath Analysis Laboratory (NEBAL)

The NEBAL is part of the Victoria Police EBA laboratory. NEBAL is appointed as both an approving authority and certifying authority for EBAs.

## 2.4 National regulations and national legislation

OIML R 126 uses the terms 'national regulations' and 'national legislation' to describe relevant regulations and legislation in force in a jurisdiction.

In Australia, these terms refer to all relevant legislative instruments and subordinate requirements concerning the control of EBAs. They include the *National Measurement Act 1960* (Cth) and NMI R 126.

## 3 Explanation of key differences

### 3.1 Previous editions

In December 2000, the then National Standards Commission published NSC R 126:2000. This was a modified adoption of the international standard OIML R 126:1998. There were some minor editorial changes through to the updated version of the document, NMI R 126:2013.

The NMI R 126:2013 (and NSC R 126:2000) requirements that differ from those of OIML R 126:1998 are as follows:

- a) NMI R 126:2013 had a different definition for what was a 'measuring cycle'. It did not contain Annex I 'Advisable provisions for the measuring cycle (informative)'. This eliminated the option to use multiple samples to detect the possibility of alcohol in the upper respiratory tracts (mouth alcohol)
- b) different measurement units
- c) that the instrument shall detect and not provide a result where mouth alcohol is present, where OIML R126:1998 had this as an option
- d) measurement range set to at least 0.500 g/210 L
- e) printing device made mandatory
- f) minimum volume of 1 litre (rather than 1.5 litres)
- g) the period of validity of certification set at 12 months.

In 2012, OIML published a revised edition of the OIML R 126 document. However, the NMI did not consider the 2012 edition to be suitable for use in Australia. As a result, the NMI did not adopt it as the pattern approval requirements for EBAs.

### 3.2 Current editions

In 2021, OIML published a new edition of OIML R 126, which was more robust than the 2012 edition. It built on the earlier 1998 edition and drew more upon other international standards for the performance and disturbances testing. It also provided an increased focus for software evaluation and integrity.

Australia has a very robust system for the use of evidential breath analysers, which is supported by the introduction of instruments complying with NMI R 126:2013. Adopting the latest (2021) international standard will better support the introduction of new instruments to the Australian market.

### 3.3 Key differences between OIML R 126:2021 and NMI R 126:2025

The NMI R 126:2025 requirements that differ from those of OIML R 126:2021 are as follows:

- a) NMI R 126:2025 places requirements on EBAs with respect to:
  - alcohol in the upper respiratory tract (residual mouth alcohol) or regurgitation
  - measurement of end expiratory breath (deep lung air), and
  - drift or shift in accuracy.
- b) The presence of alcohol in the upper respiratory tract (also called residual mouth alcohol) and end expiratory breath shall be established during the continuous monitoring of each single breath sample.

- c) The EBA shall be equipped with a function that automatically detects whether the measurement result is affected by the presence of alcohol in the upper respiratory tract (also called residual mouth alcohol).
- d) The measurement cycle of an EBA shall include the confirmation of zero measurement condition prior to and after the provision of the breath sample. In support of the measurement cycle, the EBA shall automatically perform a zero-value test or check the zero value before and after each measurement.
- e) In Australia, data storage is made mandatory, and the presence of a printing device is made optional.
- f) The Australian legal units of measurement of grams per 210 litres of exhaled breath (g/210 L) are used rather than milligram per litre of exhaled breath (mg/L).
- g) The values of requirements such as measurement ranges, scale intervals and MPEs have been converted to units of g/210 L.
- h) The minimum value of the volume of exhaled breath shall be 1.0 L, rather than 1.2 L.
- i) EBAs shall be tested with the following additional physiological influence substances: acetaldehyde, toluene, ethyl acetate, methane, and diethyl ether.
- j) The supply of an instruction manual for each individual instrument is optional.
- k) The recalibration period is specified in the NMI certificate of approval.

## 3.4 Key differences between NMI R 126:2013 and NMI R 126:2025

Changes from NMI R 126:2013 to NMI R 126:2025 are as follows:

- a) Software requirements and evaluations methods are now specified in greater detail.
- b) The masking range is not limited to 0.010 g/210 L or less.
- c) A new test is introduced to check for any effect of repeated wet samples at low temperature conditions.
- d) Changes have been made to the classification, description, and conditions of influence factors.
- e) Changes are made to the classification, description, and conditions of disturbances.
- f) Optional tests for specific environmental conditions are introduced.
- g) Specific requirements have been introduced for EBAs powered by internal batteries.
- h) Data storage is a mandatory requirement.
- i) The use or presence of a printing device is optional.

## 3.5 Timeline for transition from NMI R 126:2013 to NMI R 126:2025

The following timeline is provided to inform the implementation of NMI R 126:2025 as Australia's pattern approval requirements document and the transition process to replace NMI R 126:2013.

**1 July 2025:** Adoption and publication of NMI R 126:2025.

- The date NMI R 126:2025 is published on the NMI website.

**1 July 2025:** Applications for approval of **patterns** and **variants** to NMI R 126:2025 accepted.

- The effective implementation date for the new NMI R 126:2025 to be used to approve EBAs.

**1 July 2027:** Applications for approval of **patterns** to NMI R 126:2013 no longer accepted.

- New **patterns** of EBAs will not be approved in accordance with NMI R 126:2013 based on applications received on or after this date.
- This means that applicants will only be able to apply for approval of new patterns in accordance with NMI R 126:2025 on or after this date.

**1 July 2035:** Applications for approval of **variants** to NMI R 126:2013 no longer accepted.

- New **variants** will not be approved in accordance with NMI R 126:2013 based on applications received on or after this date.
- This means that approval holders will only be able to apply for approval of variants in accordance with NMI R 126:2025 on or after this date.
- This is the effective end date of NMI R 126:2013 as a pattern approval requirements document.

## 4 Pattern evaluation and pattern approval

Pattern evaluation is the process where an impartial body examines the design of a measuring instrument against national or international standards and/or requirements. In Australia, these standards are generally adopted from OIML Recommendations (e.g. OIML R 126) and published as national pattern approval requirements documents (e.g. NMI R 126). This evaluation then informs a decision to approve the pattern, or not.

The key requirements that are examined as part of pattern evaluation are that:

- a) the pattern complies with the relevant pattern approval requirements document, and
- b) the pattern is suitable for its intended use.

Compliance with the relevant pattern approval requirements document helps inform a decision about its suitability. There are other considerations concerning the pattern, its design, operation and intended use that must be taken into account as part of the pattern evaluation process.

Where a pattern is found to satisfy the above requirements, it may be approved for legal use in Australia. This pattern approval is evidenced by the publication of a [certificate of approval](#) on the Department of Industry website.

### 4.1 Pattern approval process for EBAs

The following guidance should be read in conjunction with NMI P 106 and NMI R 126.

- NMI P 106 *Procedures for the Approval and Certification of Patterns of Measuring Instruments* describes the pattern approval process. It is available on the [Pattern approval page](#) on the Department of Industry website.
- NMI R 126 contains specific requirements for the pattern approval of EBAs.

A person may apply to NMI for the approval of a pattern of an EBA. The application process is on the [Pattern approval page](#) on the Department of Industry website.

To support the pattern evaluation, NMI requires information about the pattern as well as a physical sample of the pattern.

For example, the following may be required as part of a pattern approval application:

- a) technical specifications of the EBA, including rated operation conditions, indications, etc
- b) relevant manuals and operating instructions
- c) images (for inclusion on the final certificate) showing the EBA, indicating device, any other relevant components, and required markings
- d) details and images of sealing provisions
- e) software and firmware information
- f) technical drawings, diagrams and component lists
- g) at least one (1) physical sample for evaluation and/or testing purposes.

### 4.2 Testing and test reports for EBAs

As part of the pattern approval process, a physical sample of the pattern of an EBA must be tested in accordance with NMI R 126-2. The testing must demonstrate compliance with the metrological and technical requirements of NMI R 126-1. The laboratory that performed the testing must issue a test report in accordance with NMI R 126-3.

Appendix 1 of NMI P 106 sets out the requirements for applications for pattern approval. For EBAs, NMI may accept test results and test reports from Tier 1 testing facilities only. NMI will not accept test results or test reports from Tier 2, 3 or 4 testing facilities.

In summary, this means that NMI may accept test reports from the following laboratories only:

- a) the NMI Australia Pattern Approval Laboratory
- b) NMI appointed approving authorities
- c) OIML Certification System test laboratories that are approved under Scheme A for OIML R 126:2021 with the exception of manufacturer test laboratories.

## 4.3 Variants of approved patterns

A variant is an addition, removal and/or modification to a component of an existing approved pattern of an instrument. Examples of possible variants include:

- a) changes to hardware such as indicating devices, instrument housings, measurement transducers
- b) changes to software versions that impact the metrological performance or metrological operations of the instrument (including indication of the measurement result)
- c) changes to ancillary devices such as printers and other legally relevant indications that are specified on the certificate of approval.

## 4.4 Approval of variants

The approval holder (the person or company named on the certificate of approval) may apply to NMI for the approval of a variant to the existing approval. Only the approval holder (or their authorised representative) can submit an application for a variant to an approval that they hold. The approval holder may authorise a third-party representative to submit and progress an application on their behalf, including the payment of fees. This authorisation needs to be submitted to NMI in writing.

An application for the approval of a variant is handled in a similar manner as an application for the approval of a pattern. However, the pattern evaluation and any required testing will be subject to:

- the design of the variant, and
- how it may change the measurement design and performance of the existing approved pattern (and approved variants).

An approved variant is documented in a certificate of approval. The certificate describes the design change or modification to an approved pattern. Examples include a different indicating device or different software version. Variants are approved for legal or trade use just like the original pattern. They simply provide for a convenient way of documenting design changes within certificates of approval, rather than issuing a new certificate every time a design is updated.

Approval holders should contact NMI whenever there are design changes to approved patterns of measuring instruments that they hold. They can contact NMI for advice about:

- whether a design change to a pattern should be documented as a variant in a certificate of approval
- if the change requires a new certificate of approval to be issued.

Alternatively, an approval holder can submit an application for a variant (or a new certificate) without prior advice from NMI.

## 4.5 Amendments to certificates of approval

An amendment is generally considered a minor change to a certificate of approval. This may include minor corrections or updates to the pattern or variants, contact details of the approval holder, or other clarifying information.

The approval holder may apply to NMI for amendments to their certificate of approval.

## 5 Certification process

### 5.1 Initial certification

This is defined as 'Initial Verification' in NMI R 126-2, section 3.1.1.

Every new instrument sold in Australia that is to comply with NMI R 126 shall be subjected to initial certification testing. The testing is a sub-section of the NMI R 126 tests. It is carried out to ensure compliance to NMI R 126 and monitor for any potential faults in each instrument.

The testing is conducted by the National Evidential Breath Analysis Laboratory (NEBAL). The cost of testing for Australian state and territory police services is covered by their annual contribution to the running of NEBAL.

External customers will be charged a fee, usually through the manufacturer or supplier at the time of instrument purchase.

### 5.2 Periodic certification

This is defined as 'Subsequent Verification' in NMI R 126-2, section 3.1.2.

Periodic certification is the ongoing calibration of EBA instruments. The certifications are valid for intervals as defined in the NMI certificate of approval (generally 12 months).

The calibrations are carried out by appointed certifying authorities. The manufacturer and the laboratories define the calibration and service methods to ensure the ongoing compliance with the requirements of the standard. A particular focus is to ensure the ongoing accuracy of the results produced. The laboratories should be NATA accredited for the calibration of EBA instruments and appointed by NMI (under the authority of the Chief Metrologist) as certifying authorities.

### 5.3 Certifying authorities

Certifying authorities are appointed by the Chief Metrologist under the National Measurement Regulations 1999 (Cth). A key requirement for the appointment of a certifying authority is the demonstration and maintenance of their competency. Under Regulation 73, the Chief Metrologist may appoint an applicant as a certifying authority that:

- a) in the opinion of the Chief Metrologist, is capable of, or has direct control of staff who are capable of, certifying measuring instruments and/or certifying reference materials, or
- b) holds NATA accreditation that the Chief Metrologist considers appropriate to the functions mentioned in paragraph (a).

NATA accreditation is the recommended and standard means to demonstrate competency and capability in supporting an application to become appointed as a certifying authority.

More generally, NATA is:

- Australia's leading national accreditation body
- recognised by government as a national authority
- Australia's sole signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).

NATA is the recommended accreditation service provider for this purpose.

# 6 Roles and responsibilities

## 6.1 Responsibilities for certifying authorities

### 6.1.1 Certification

Certifying authorities have an obligation to ensure that the instruments that they certify under Regulation 37 of the National Measurement Regulations 1999 (Cth) are of an approved pattern.

At a minimum, certifying authorities should ensure that the instrument to be certified is marked with a pattern approval number corresponding to a certificate of approval issued by NMI. Certifying authorities should also perform a visual inspection of the instrument to check if it is consistent with the pattern described in the certificate of approval. Additional checks of instrument documentation and functions can serve to improve confidence that the instrument is of an approved pattern.

An instrument is considered to be of an approved pattern if it is:

- marked with a pattern approval number, and
- conforms with that approved pattern.

An instrument that is not of an approved pattern must not be certified by a certifying authority.

A certifying authority may contact NMI to enquire about the apparent conformity or approval status of an instrument or pattern. NMI can confirm that an instrument appears to conform to an approved pattern, and the status of the pattern approval. NMI may not be able to provide a more detailed response because pattern approval applications are confidential.

If a certifying authority observes that an instrument submitted for certification under Regulation 37 does not appear to conform to a pattern specified in a certificate of approval, they must:

- a) not certify the instrument (Regulation 37), and
- b) notify the supplier in writing of the decision to not certify the instrument and the reason for that decision (Regulation 38).

### 6.1.2 Reporting

Separately, the Chief Metrologist (or their delegate) may request information from certifying authorities be reported regarding certification activities (Regulation 77). These requests will be made in writing at the time. This may include information regarding instruments that were submitted for but did not meet the requirements of certification under the National Measurement Regulations 1999 (Cth). Beyond this, certifying authorities may advise the supplier that they should contact NMI to clarify whether the certificate of approval is up-to-date and reflects any recent design changes. Relevant changes include changes to hardware, software or firmware.

### 6.1.3 Responsibilities and services provided by the National Evidential Breath Analysis Laboratory (NEBAL)

The NEBAL is also known as the National Laboratory. It is part of the Victoria Police EBA laboratory. It was established on agreement of all the Australian state and territory police services in 2002 after the introduction of NSC R 126:2000. Its purpose is to assist type approval testing and conduct initial certification of all Australian EBA instruments. The laboratory also provides proficiency testing to all EBA certifying authorities and liaises with manufacturers, suppliers, NATA and NMI.

As a certifying authority and approving authority, the laboratory is subject to the obligations and reporting requirements outlined in this document. They will also be subject to the specific conditions of their appointments.

## 6.2 Responsibilities for approval holders

### 6.2.1 Approved patterns

Approval holders are responsible for ensuring that all instruments are manufactured to an approved pattern and comply with the certificate of approval. Approval holders are also responsible for marking only instruments that comply with an approved pattern with the corresponding pattern approval mark. It is essentially a statement of conformity to the approved pattern.

The approval holder should contact NMI whenever there are design changes to approved patterns of measuring instruments that they hold. NMI will advise the approval holder whether the changes require evaluation under an application for variant or a new certificate. A new certificate will require a submission of an application form. If the design change does not require a variant or a new a certificate, NMI will retain the information and its evaluation on file. This allows NMI to provide future advice about the status of a measuring instrument or pattern.

### 6.2.2 Notifications to customers

In general, NMI does oblige approval holders to notify their customers of changes. It is generally good practice to inform customers of design changes and updates to certificates of approval that correspond and support those design changes. Approved variants are published in certificates of approval and are available on the (NMI) Department of Industry website. NMI encourages suppliers and customers to consult the certificates of approval for information about the approved patterns of measuring instruments.

### 6.2.3 Penalties associated with pattern approval

Section 19B of the *National Measurement Act 1960* (Cth) specifies penalties in relation to false representations of patterns of measuring instruments, specifically:

- marking an instrument with an approval number that does not comply with the approved pattern, or
- marking an instrument with an approval number when not authorised to do so.

In addition, the *National Measurement Regulations 1999* (Cth) allows the Chief Metrologist to cancel or withdraw approvals of patterns of measuring instruments that are found to be not suitable for their intended use.