

Frequently Asked Questions about European Reference Materials ERM®



Why? - What is the “big idea” behind European Reference Materials?

Currently there are many European reference materials producers that are individually centres of competence. Most of these offer quite restricted ranges of products and are not widely recognised internationally. By uniting under the European Reference Materials ERM® brand they are able to pool their knowledge and resources and present a strong European brand to an international audience. Through adoption of the latest principles of production and certification and thorough peer review it is possible to offer an increased range of internationally-recognised, high quality certified reference materials (CRMs).

What is an ERM® branded material?

An ERM is a CRM with the added value that very stringent quality criteria regarding production, homogeneity and stability testing, and of course characterisation measurements, have to be fulfilled. A special panel made up of leading experts in the field scrutinises every application before the ERM® label is granted.

What is the difference between CRM, RM, SRM, ERM?

Reference material (RM) is the generic term for a group of either pure substances or matrix materials, which are used for calibration, method validation, the establishment of traceability, method development, and various quality control purposes (proficiency testing, charting, etc). If the reference material fulfils a number of requirements (proven homogeneity and stability, characterisation of the property values using suitable, well described and validated methods) this information may be summed up in a certificate, thus being a certified reference materials.

SRM is a trademark registered by the US National Institute for Standards and Technology (NIST) for the certified reference materials they produce and stands for Standard Reference Material. An ERM belongs to the group of CRMs which carry the trademark ERM®.

What is a CRM?

Briefly, a certified reference material (CRM) is a material which is used either for method validation, in particular to check for method bias, or for calibration. The formal answer - as defined in the corresponding ISO Guide is:- a CRM is a reference material characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.

What are the main benefits of buying an European Reference Materials?

Users can have confidence in the certified values and their uncertainties as a result of the demanding criteria and rigorous scrutiny that each certified value is given. The producers are committed to making sure that the certification process is transparent for all. This aspect together with the clearly defined and stated traceability of the certified values will provide users with the information they need to fully evaluate the suitability of a particular CRM for their application.

How does a product become an ERM®?

In order to be included in the ERM® range a certified reference material (CRM) must satisfy a number of demanding criteria with respect to the production of the material, the way in which it was characterised, its homogeneity and stability. These criteria are specified in ISO Guides 34 and 35. A panel of leading experts in the field of reference materials scrutinises all applications to ensure only the highest quality products become ERMs

What does the shelf-life mean?

Producers of reference materials guarantee within a specified time (=shelf life) the integrity of the material and the validity of the certificate accompanying the material, provided the sample is properly transported and stored. Furthermore, most producers guarantee this only for materials in an unopened container. In other words, once the original material container is opened material integrity can no longer be guaranteed. This does not automatically mean that the user has to throw away the unused sample. Normally, the material will remain stable when stored under suitable conditions.

For what applications are ERM® CRMs suitable?

The ERM® range of reference materials covers the following applications: environmental, food/agriculture, industrial and clinical. There are also calibration standards certified for purity, concentration, and activity, or for physical properties including melting point, hardness and optical properties.

What does traceability mean for Certified Reference Materials (CRMs)?

The International Vocabulary of Metrology defines traceability as the property of a measurement result whereby the result can be related to a reference through an unbroken chain of calibrations, each contributing to the measurement uncertainty. In more practical terms this means to anchor the results to standards which do not change over time and place in order to make measurement results comparable. Consequently, the certified value(s) of a CRM shall be traceable to such internationally accepted standards, preferably to the SI. Use of a CRM is a convenient way to demonstrate traceability.

If the property value of the CRM is traceable to e.g. the SI, then these measurement results provide traceability to SI units. However, this is only valid if the uncertainty of the property values of the CRM are properly taking into account and if the nature of the sample are sufficiently matched by the analyte level/matrix of the CRM.

What does the CRM uncertainty mean? How do I use it to evaluate my measurements?

The uncertainty indicates the range where the “true” property value can be expected with a certain probability. This information can directly be used, if the material is used for calibration. When the material is used to estimate method bias, the uncertainty range for the result obtained in the laboratory of the user should overlap with the uncertainty range given on the certificate. If this is true, the method applied by the user for determining the property is unbiased.

What should I do with opened materials?

Opened materials should be stored under the recommended storing and safety conditions as given on the corresponding certificate.

How should I use the data obtained on measurements of a Certified Reference Material (CRM)?

There are several possible uses for the data obtained from a measurement of a CRM. It can be used to:-

- Validate a method of measurement. This is to see if the observed value and the certified value agree within the uncertainty.
- Verify a specific measurement procedure. This is to see, if the observed value and the certified value agree within the uncertainty under the specific laboratory conditions.
- Control the accuracy of measurements within the uncertainty.
- Calibrate a measurement device for a specific type of measurement. This is to establish the relation between a 'signal' and the quantity intended to be measured (usually a concentration). In the simplest case, a calibration factor and its uncertainty is calculated from the observed value and the certified value.
- Underpinning proficiency testing. The use of a well characterised test sample, unknown by the PT participants, enables their performance to be monitored against certified values instead of the consensus values. Moreover, the homogeneity and stability of such a PT test sample will have been characterised already.
- Develop new methods of measurement.
- Estimate measurement uncertainty.



Are European Reference Materials, ERM® only for Europeans?

No
ERM-CRMs are suitable for any user who requires reference materials of the highest level of assurance. Materials marketed under the ERM® brand will have been produced in accordance with the principles laid down in ISO Guides 34 and 35 and will have been subject to extensive review by all member organisations. ERM® materials are available from a number of reference material distributors who have international capability. But membership of the ERM® partnership is open only to reference materials producers located in the European Union who can demonstrate that they meet certain defined membership criteria.

Who owns the European Reference Materials ERM® materials?

Each ERM material is owned by one of the members of the ERM® cooperation. The owner is fully responsible for its materials i.e. production, replacement, stability, storage, product liability, etc.

When did it start?

The launch of the ERM® range took place in May 2004 at Analytica 2004 in Munich, Germany. A special catalogue containing the first 146 certified reference materials was produced for the occasion.

Who is involved? Who are the members of the ERM® cooperation?

The founding partners of the ERM are three well-reputed measurement institutes, namely the Institute for Reference Materials and Measurements (IRMM), an institute of the European Commission's Joint Research Centre, LGC the United Kingdom's designated national measurement institute for chemical and biochemical analysis, and the Federal Institute for Materials Research and Testing (BAM), a technical and scientific senior federal institute under the authority of the Federal Ministry of Economics and Labour in Germany.

Is the ERM® concept only for EU CRM producers?

The Trademark owner (European Community) is not prepared to give a licence for the trademark to an institute outside the EU.

What is the CIPM-MRA?

The CIPM-MRA is a document of mutual recognition of measurement results in different countries, and was set up by the 'International Committee of Weights and Measures', the highest authority in measurements following the Metre Convention.

The CIPM-MRA www.bipm.org/en/convention/mra/objectives.html is:-

- establishing the degree of equivalence of national measurement standards maintained by signatories
- providing the mutual recognition of calibration and measurement certificates issued by signatories.
- thereby providing governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs.

What are signatories/designated laboratories of the CIPM-MRA?

Signatories of the CIPM-MRA are the legal representatives of the highest authority for measurements in their country. Typically these representatives are the directors the National Measurement Institutes (NMIs). For specific fields of measurements, the representatives can designate other laboratories as authority in their country.

Signatories/designated laboratories are listed:
www.bipm.org/utis/en/pdf/signatories.pdf

Is the ERM® cooperation a closed club?

ERM® is not a closed club, but explicitly open to new members, who fulfil the defined membership criteria as given under www.erm-crm.org. The summarised criteria are:

- Be located within the European Union and be a signatory or designated laboratory of the CIPM-MRA.
 - Be a producer of certified reference materials who fulfils agreed quality standards, in particular by having in place a quality system for the production of CRMs in accordance with ISO Guide 34 and 35.
 - Accept all principles of the ERM® Memorandum of Understanding.
- The role of the three 'founding' partners is as the nucleus of the ERM®.

Who owns the trademark?

The European Community owns the ERM® trademark. The Community licences the trademark to the ERM® partner organisations to mark products accepted as ERM® in accordance with the ERM® rules.

When does the trademark expire?

The ERM® trademark is licensed to member organisations for the duration of the ERM® co-operation provided the licensee continues to remain a member of the co-operation and to follow its rules. Licensees are obliged not to use the Trademark for any materials, which are not accepted as ERM®.

How to find out more about European Reference Materials
Please visit www.erm-crm.org