



Definitions of types of Reference Materials and Controls

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Same language ?





Minimum RM Characteristics

Reference Materials

characteristics:

- *homogeneity (fit for intended use)*
- *stability (fit for intended use)*

No further characteristics

= QCMs

Quality control Materials

In-house materials

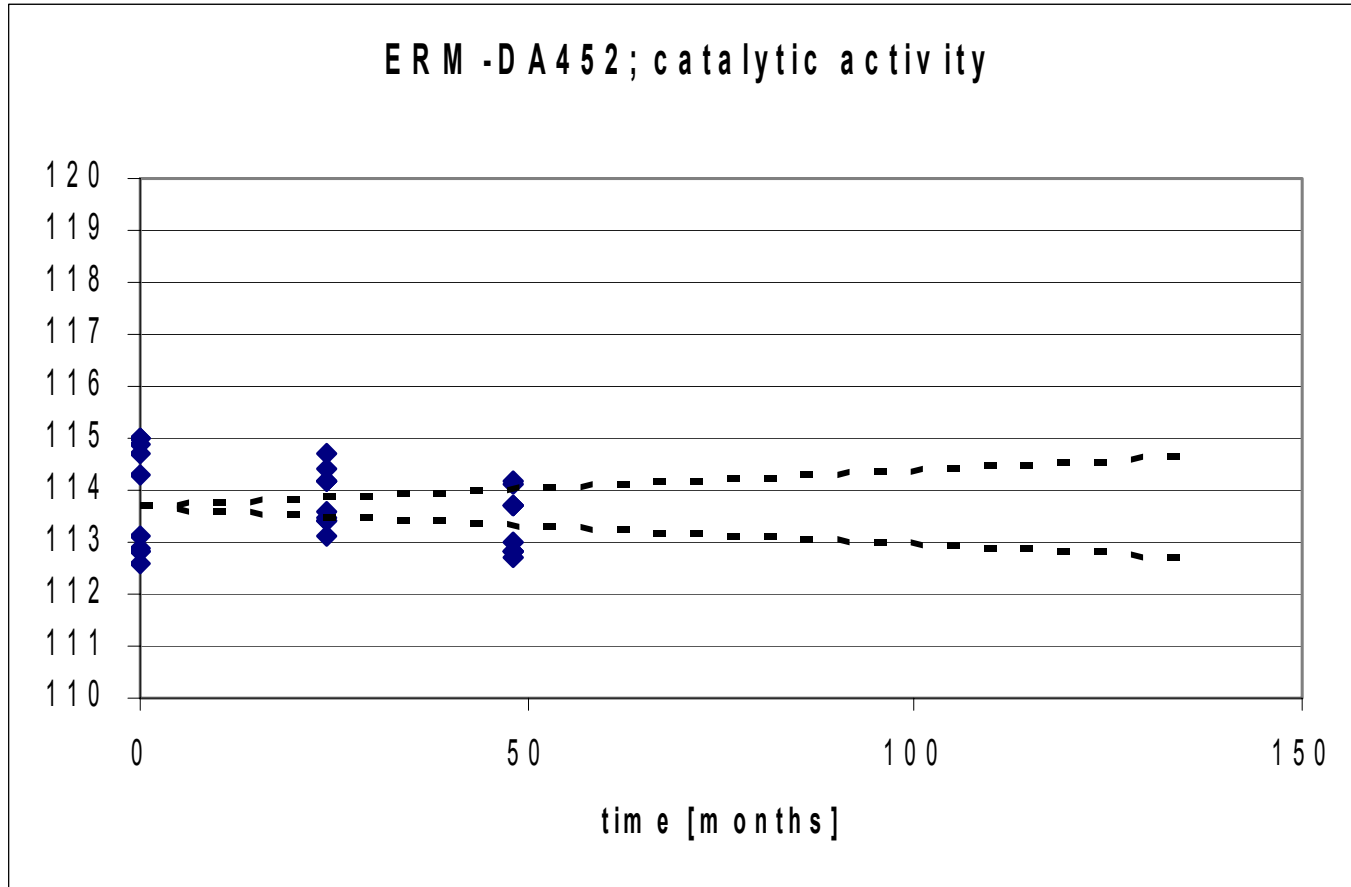
Laboratory control materials

Laboratory reference materials

Material for EQAS



Stability study



\pm Sdt error slope x t

max tolerated u_s



RM Shelf-live

γ -glutamine transferase





Reference Material (RM)

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Notes: 1) RM is a generic term.

2) Properties can be quantitative or qualitative, e.g. identity of substances or species.

3) Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

4) An RM can only be used for a single purpose in a given measurement.

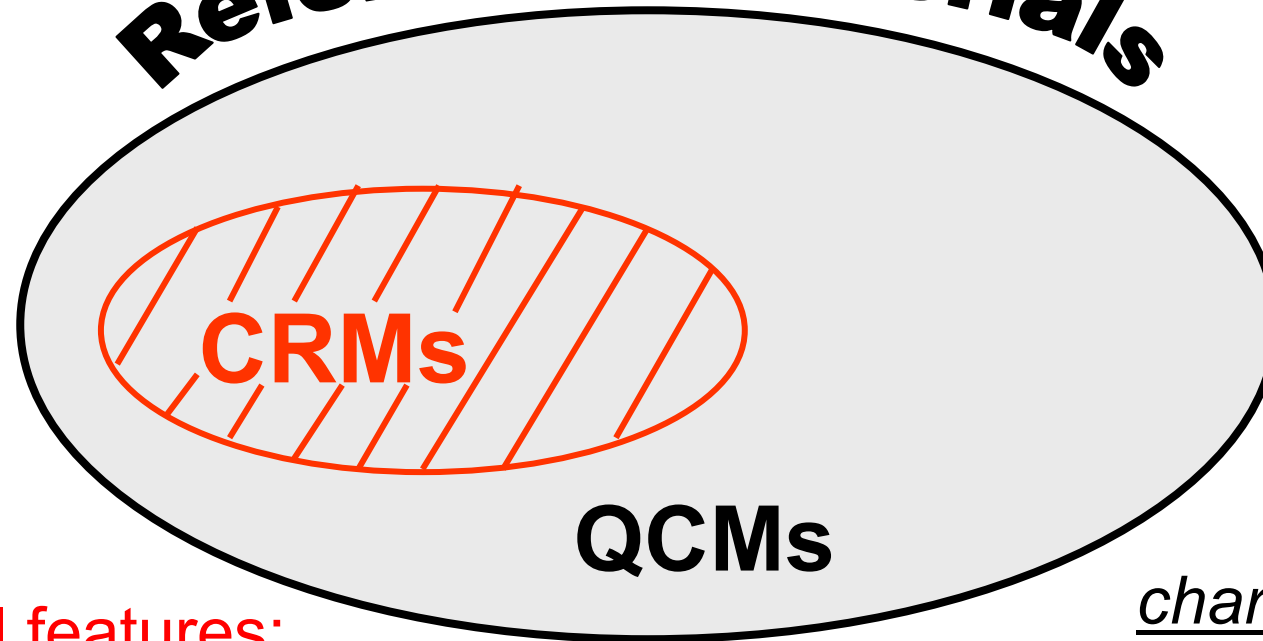
ISO Guide 35 (2005)





Certified Reference Materials

Reference Materials



additional features:

- certificate
- certified value with uncertainty
- stated traceability

characteristics:

- *homogeneity (fit for intended use)*
- *stability (fit for intended use)*



Certified Reference Material (CRM)

An RM characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that states the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

- Notes:
- 1) The concept of values includes **qualitative** attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.
 - 2) Metrologically valid procedures for the production and certification of reference materials are given in among others ISO Guides 34 and 35.
 - 3) ISO Guide 31 gives guidance on the contents of certificates.

ISO Guide 35 (2005)





The “RM Family”

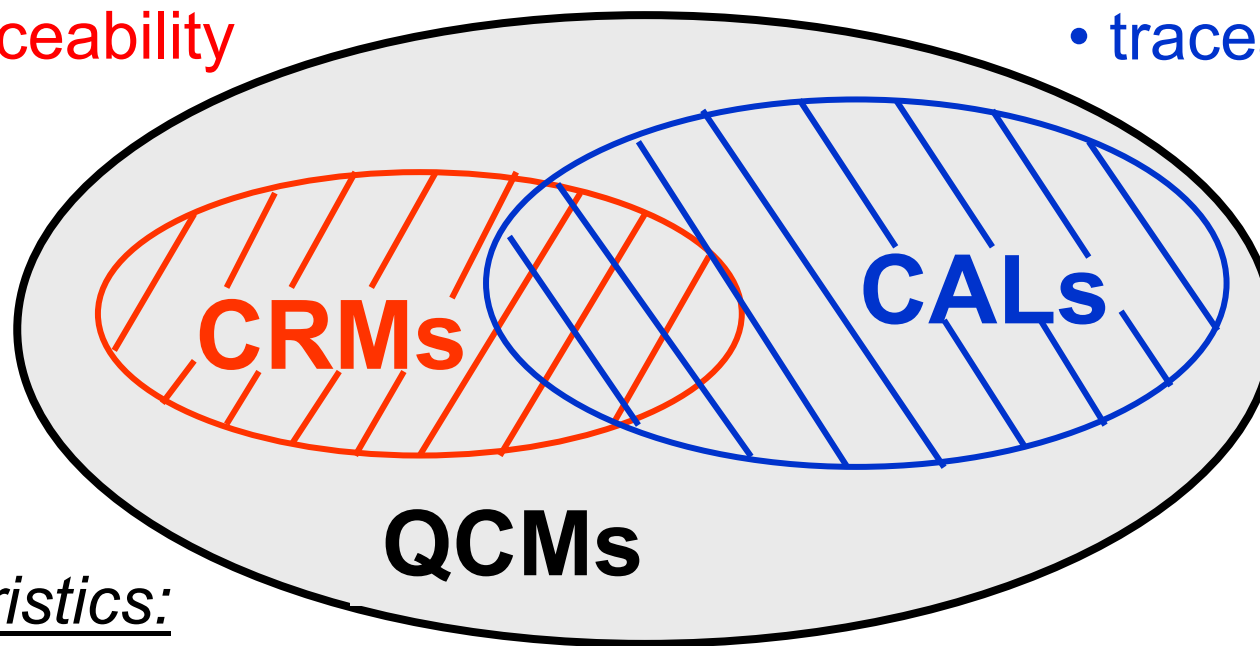
additional features:

- certificate
- certified value with uncertainty
- stated traceability

CRMs with uncertainties of property values fit for calibration

additional features:

- property value with uncertainty
- traceability



characteristics:

- *homogeneity (fit for intended use)*
- *stability (fit for intended use)*

H. Emons:
ACQUAL
(in print)





Uses of Reference Materials

- **Method development and validation**
 - evaluation of trueness
 - uncertainty estimation
- **Calibration**
- **Proof of method performance**
 - statistical quality control
 - establishing traceable results
 - equipment qualification
- **Proficiency testing**
 - training and verification of competence



Definitions of IVDs

NOT COVERED

- CRMs
- materials used for EQA schemes

COVERED → need of CE Mark

- Calibrators, control materials needed to establish or verify performance of devices.

—————→ **Sold as part of a kit**



Annex1.3 : Essential requirement

The traceability of values assigned to **calibrators** and/or **control materials** must be assured through :

- available reference measurement procedures

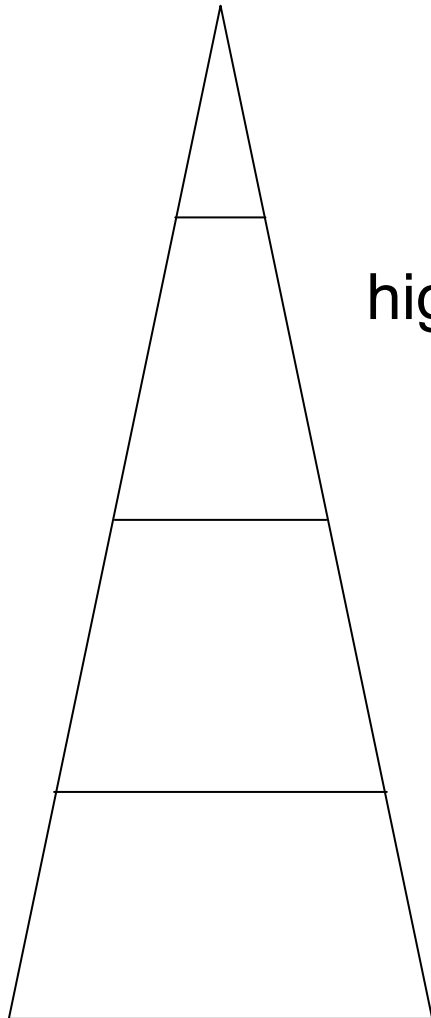
and/or

- available **RM** of a higher order.



RM of higher order for GT ?

ISO17511 : IVD calibrators should be traceable to :



SI unit

higher order reference measurement procedures
(eg. robust method)

conventional RM
(eg WHO international standard)

“in-house” method and calibrants
QCM