EUROPEAN COMMISSION
DIRECTORATE-GENERAL
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Definitions of types of Reference Materials and Controls

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Same language ?

Minimum RM Characteristics

Reference Materials

characteristics:

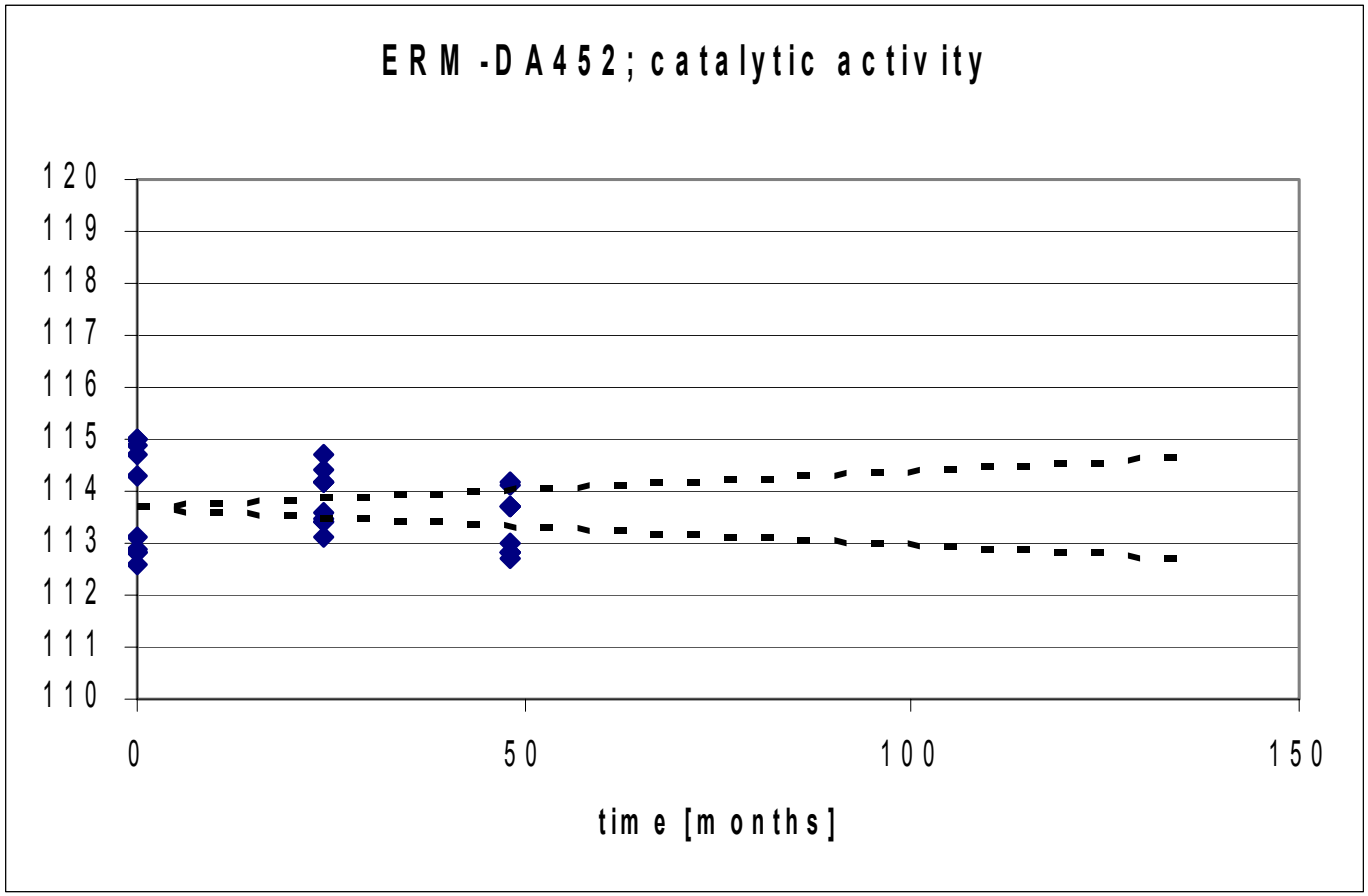
- *homogeneity (fit for intended use)*
- *stability (fit for intended use)*

No further characteristics **= QCMs**

Quality control Materials

- In-house materials
- Laboratory control materials
- Laboratory reference materials
- Material for EQAS

Stability study



± 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.

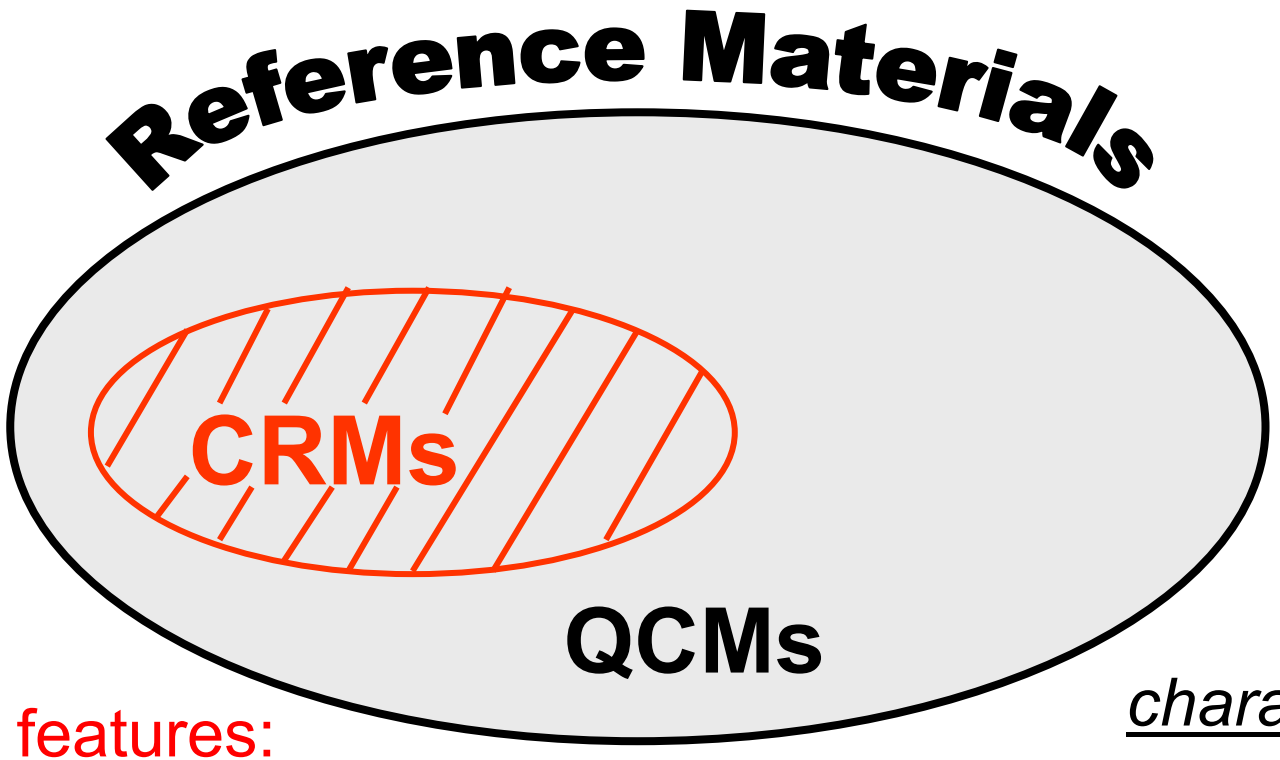
2) Properties can be quantitative or qualitative, e.g. identity of substances or species.

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



<u>additional features:</u>

- certificate
- certified value with uncertainty
- stated traceability

<u>*characteristics:*</u>

- *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"

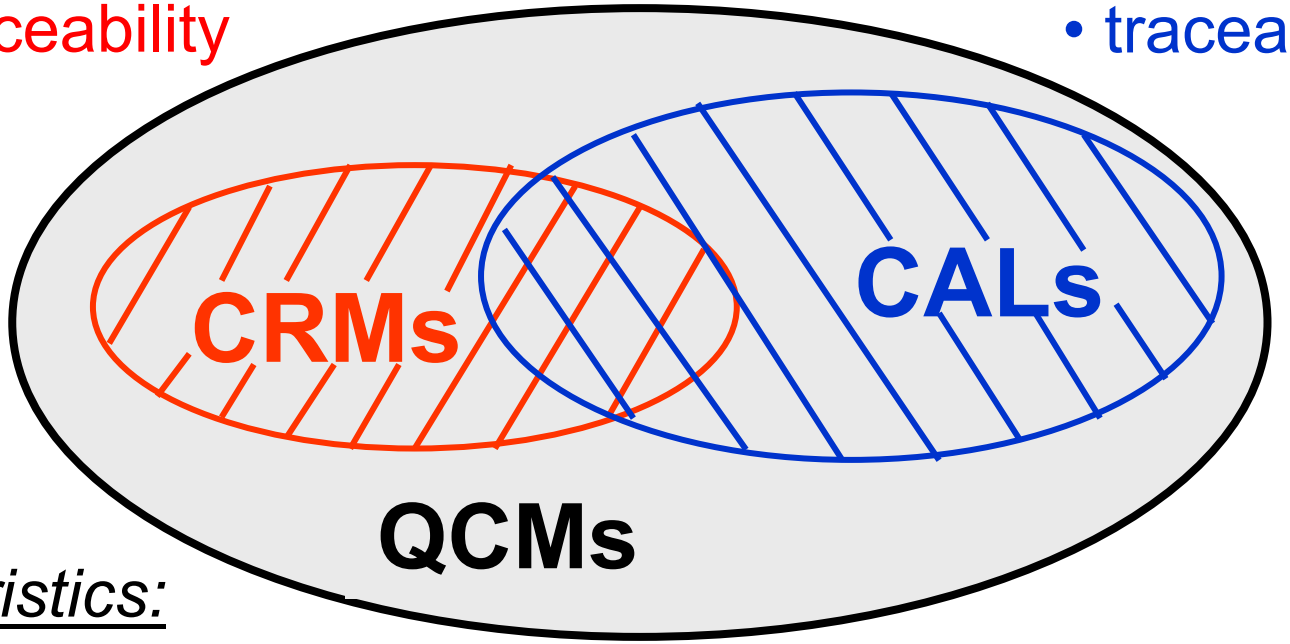
additional features:

- 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 :

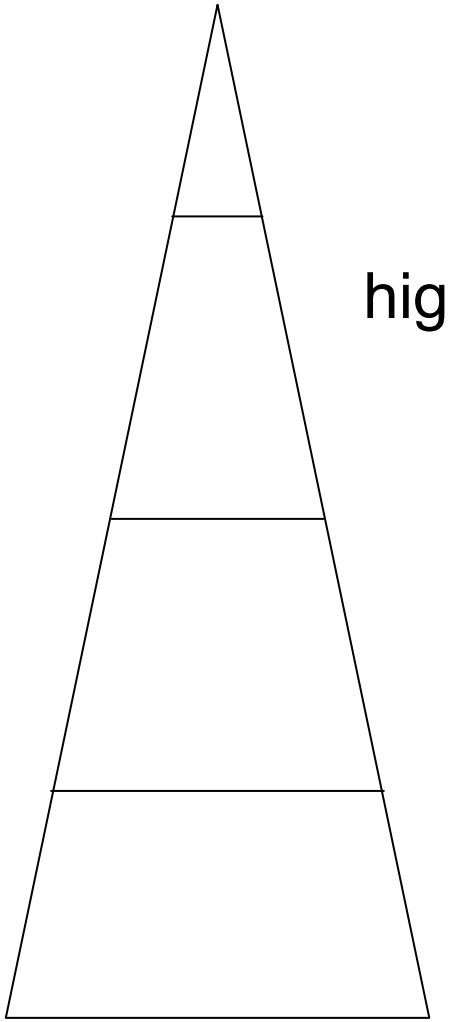
- available reference measurement procedures

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