

Accreditation of companies to  
production of reference materials

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## 1. Application

**1.1** This accreditation regulation applies to DANAK's accreditation of companies to production of reference materials in accordance with DS/EN ISO17034, General requirements for the competence of reference material producers.

## 2 Scope of accreditation

**2.1** For companies accredited to production of reference materials the scope of accreditation specifies which services each accreditation comprises. The scope of accreditation appears in the decision on accreditation and is published on DANAK's homepage.

**2.2** It appears from the scope of accreditation whether the assigned values for reference materials are determined based on measurements carried out by the company (or its sub-contractor(s)), which would apply for reference materials, where the values are determined by metrological traceable calibration/testing, or whether the assigned value is determined by collective measurements e.g. based on the results from interlaboratory comparison.

**2.3** Furthermore, it appears from the scope of accreditation which type of reference material it concerns. Certified reference materials are indicated by "CRM" under comments in the list of materials, while "RM" indicates reference materials that are not certified. "CRM and RM" indicate materials, which are both CRM and RM.

## 3. Requirements for accreditation to production of reference materials

**3.1** The laboratory and its sub-contractors, if any, shall comply with relevant requirements in DS/EN ISO 17034 and related DANAK accreditation regulations.

**3.2** The measurements that are the basis for determining the ascribed values shall be carried out in compliance with the requirements in DS/EN ISO/IEC 17025 as well as relevant parts of DANAK's accreditation regulations for test- and calibration laboratories. This comprises in addition to measurements to determine ascribed values, homogeneity, stability etc. also measurement of influence parameters. Collective measurements which are basis for the ascribed values can be chosen on the basis of ISO Guide 35.

## 4. Metrological traceability

**4.1** As documentation for metrological traceability to SI units companies may use certificates from accredited calibration performed by a laboratory accredited by an accreditation body included in EA's multilateral agreement (EA's MLA) and ILAC's agreement on mutual recognition (ILAC's MRA) within calibration. Laboratories may as well use certificates from calibration performed by a national metrology institute included in CIPM's MRA for the service in question.

**4.2** Companies which establish traceability to results from internal calibration shall observe the requirements to estimation of uncertainty in DANAK Accreditation Regulation AB 11 Uncertainty of measurement in calibration.

**4.3** Companies which cannot establish traceability to SI-units may use traceability to i.e. certified reference materials, agreed methods and/or standards or reference materials based on consensus.

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## 5. DANAK's assessment

**5.1** If the company accredited to production of reference materials is part of an accredited laboratory or part of a company having an accredited laboratory within the area, DANAK's surveillance and renewal visit will as far as possible be conducted in connection with surveillance and renewal of the company's other accreditation in this area.

## 6. References

Section 2.2 and 2.3: DS/EN ISO/IEC 17011 section 7.8.3

Section 3.1: DS/EN ISO/IEC 17034

Section 3.2: DANAK

Section 4: ILAC P10

Section 5: DANAK

The Accreditation regulation came into force 16 September 2019. Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.