GUIDELINE

Proficiency Testing and Comparative Testing			
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1. Delimitation

This guideline is valid for all accredited laboratories and for laboratories applying for accreditation according to DS/EN ISO/IEC 17025 or DS/EN ISO 15189.

2. Purpose

DANAK's Guidelines expresses the interpretation of accreditations standards etc., which DANAK wishes to imply to ensure harmonisation of the terms, which apply to accredited laboratories. DANAK shall prior to deviation of the Guideline accept, that another interpretation of the terms will fulfil terms in question of standards etc.

The purpose of this Guideline is to describe how laboratories through participation in Proficiency Testing verifies, that the Management system ensures satisfying results.

3. Definitions

Proficiency Testing: Common designation for Interlaboratory Comparisons (ILC), Proficiency Testing (PT) and External Quality Assurance (EQA).

Comparative Testing: Common designation for comparative testing, calibration or medical examination. A Laboratory can take initiative to a comparative testing or can participate in interlaboratory studies etc.

4. General

It is the responsibility of each laboratory to take initiative to participate in the relevant Proficiency Testing programmes provided. DANAK will asses the laboratories participation and the results thereof.

In areas where participation in Proficiency Testing is not accessible, the laboratory must document credibility of measurement or examination in other manners. The laboratory should identify those areas. The laboratory might document credibility by e.g. participation in interlaboratory studies.

The Laboratory might also participate in bilateral comparative testing. For Calibration Laboratories it should be ensured, before engagement in such an activity, that the Laboratory for comparison has better or at least equal best measurement capability as the Laboratory itself.

An accredited Laboratory should participate in Proficiency Testing that in a reasonable degree covers the accredited scope. For Laboratories applying for accreditation, documentation of satisfactory results in Proficiency Testing should be available or, where Proficiency Testing is not accessible, other documentation of credibility of measurement, e.g. comparative testing.

5. Preparation of Policy, Procedure and Plan for participation in Proficiency Testing and Comparative Testing.

Policy:
The Laboratories policy for participating in Proficiency Testing shall fulfil the requirements of DS/EN ISO/IEC 17025, section 5.9 or DS/EN ISO 15189, section 5.6, legal demands and other relevant documents.

The Policy should ensure that the Laboratory participates in Proficiency Testing in sufficiently extent to cover the accredited scope. It should be secured that sufficient resources are allocated for work related to the participation in Proficiency Testing. The Policy should consider that the duty of information, i.e. TF 4, with respect to DANAK is observed and that cooperation between the Laboratory and DANAK is satisfactory. The commitment of the Management to comply with relevant demands should be stated.

Procedure:
The Procedure should be elaborated in such a manner that Proficiency Testing is chosen in a sufficiently extend, that the relevance is considered and that plans for participating in Proficiency Testing are worked out. The Procedure should contain an approach to ensure participation in relevant Proficiency Testing including insurants of resources for this activity. In addition, the procedure should contain guidelines for evaluation and registration of results from Proficiency Testing's.

Plan:
The Plan should be elaborated in such a manner, that it is possible to consider, if Proficiency Testing covers the scope of accreditation to a relevant extent. In addition the plan should contain both historical and future activities to a relevant extent.

6. Proficiency Testing provided by DANAK

DANAK might communicate arrangement of and participation in Proficiency Testing – both national and international.

DANAK can nominate laboratories to participate in Proficiency Testing that is arranged by or recommended by European co-operation for Accreditation (EA) or International Laboratory Accreditation Cooperation (ILAC).

7. Coming into force

This guideline is coming into force 1 December 2008.

DANAK, 29 October 2008

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8. References

DS/EN ISO/IEC 17025:2005, section 5.9
DS/EN ISO 15189:2005, section 5.6
TF 4:2006 Duties of information
TF 5:2001 Recognised certificates of calibration
EA-2/10:2001 EA Policy for Participation in National and International Proficiency Testing Activities
EA-03/04:2001 Use of PT as a tool for accreditation in testing
ILAC P9:2005: ILAC Policy for Participation in National and International Proficiency Testing Activities.

9. Appendices

Appendix 1: Calculation of values

Appendix 2: Definition of sub-areas and frequency for Proficiency Testing

Annex 1

Calculation of values

For a comparative testing the so-called E_n – score is calculated by

$$E_n = \frac{x_{lab} - x_{ref}}{\sqrt{U_{lab}{}^2 + U_{ref}{}^2}}$$

where x_{lab} is the value determined by the Laboratory with a corresponding expanded uncertainty U_{lab}, og x_{ref} is the measured (or assigned) reference value with the corresponding expanded uncertainty U_{ref}. See TF 8 "Determination of uncertainty" for more information on determination of the expanded uncertainty.

If $|E_n| \leq 1$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of 95%. The result of the comparative testing is thus satisfactory. If $|E_n| > 1$ the result is unsatisfactory.

Calculation of E_n – score is traditionally used for Proficiency Testing and bilateral comparisons within calibration. I such a case should the reference value only reluctantly be determined as a weighed mean of the measurements of the participating laboratories. More information on treatment of date can be found in ISO guide 43-1.

For participation in a Proficiency or comparative testing, where E_n – score is used for evaluation of results, following conditions are essential:

- that traceability derives from an accredited laboratory, a primary laboratory or a national reference laboratory. For foreign providers the traceability should be secured according to current multilateral agreements (MLA). See also TF 5 "Recognised calibration certificates".

Calculation of *z*-score

For a comparative testing or proficiency testing, where a reference value is not available the so-called z-score is calculated by

$$z = \frac{x_{lab} - x_{ref}}{s}$$

where x_{lab} is the value determined by the Laboratory, x_{ref} is the assigned value, and s is an expression for deviation on results. The assigned value will in many cases be a weighed mean of the measurements of the participating laboratories, where statistical outliers is removed.

If $|z| \leq 2$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of more than 95%. The result of the comparative testing is thus satisfactory.
For $2 < |z| < 3$ compliance is doubtful.
If $|z| \geq 3$ the result is unsatisfactory.

Calculation of zeta-score

For a comparative testing or proficiency testing, where a reference value is not available the so-called z-score is calculated by

$$zeta = \frac{x_{lab} - x_{ref}}{\sqrt{u_{lab}^{\ 2} + u_{ref}^{\ 2}}}$$

where x_{lab} is the value determined by the laboratory, and x_{ref} is the reference value. u_{lab} is standard uncertainty on the determined value and u_{ref} is the standard uncertainty for the reference value. The reference value will often be determined by certification of a reference material or by a weighed mean of the measurements of the participating laboratories, where statistical outliers is removed.

If $|zeta| \leq 2$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of 95%. The result of the comparative testing is thus satisfactory.
For $2 < |zeta| < 3$ compliance is doubtful.
If $|zeta| \geq 3$ the result is unsatisfactory.

Annex 2

Definition of sub-areas and frequency for Proficiency Testing

Under translation!!!