

GUIDELINE

On site activities

No. : RL 5

Dato : 2001.06.20

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1. REFERENCES

DS/EN ISO/IEC 17025 (especially clauses 5.7.1-5.7.3 and 5.8.1).

2. DELIMITATION

The guideline applies to accreditation of on site activities such as testing, calibration and sampling. The guideline replaces the previous version dated 15 November 1996 and comes in effect by 1 July 2001. When this guideline comes in effect RL 6 dated 12 February 1997 and TF 10 dated 9 October 1996 are withdrawn.

3. OBJECT

DANAK's guidelines express DANAK's interpretation of relevant sections in accreditation standards, etc. with a view to ensuring harmonisation of the conditions imposed on accredited laboratories.

This guideline concerns DANAK's interpretation of specific clauses in DS/EN ISO/IEC 17025 relevant for on site testing, calibration and sampling.

4. DEFINITIONS

- 4.1 Permanent laboratory A laboratory that is set up on a specific site for a period expected to exceed 3 years. The facility from where testing/calibration normally is carried out and where administration takes place.
- 4.2 On site laboratory A laboratory that holds equipment and staff on a certain site for a period of time not expected to exceed 3 years.
- 4.3 Site Any locality where testing, calibration or sampling as defined by 4.4 or 4.5 takes place i.e. customer's premises, buildings and open spaces.
- 4.4 On site testing Testing (including sampling if part of the documented test procedure) performed by laboratory staff outside the permanent laboratory.
- 4.5 On site calibration Calibration performed by laboratory staff outside the permanent laboratory.
- 4.6 Sampling A defined procedure where a part of material, matrix or product is drawn for the purpose of testing/calibration. The sample should be representative for the material, matrix or product and fit for purpose as specified in the test procedure.

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5. CATEGORIES OF ON SITE ACTIVITIES

Two kinds of on site activities are considered:

- a) Activities handled by staff sent on site from the permanent laboratory or the on-site laboratory.
- b) Activities performed on site in a mobile laboratory in an organisation that does not have a permanent laboratory.

6. PROCEDURES AND ORGANISATION

- 6.1 If the equipment is owned by the customer or a third body a contract for access and use of the equipment must be available. It should be clear from the contract that the accredited laboratory is responsible for the maintenance and calibration of the equipment. The authorized person for on site activities should be an employee of the accredited laboratory.
- 6.2 The Management system in the laboratory shall hold procedures specific for on-site activities.

The procedures should include:

- a) up to date records of on-site activities and identification of mobile units/on site laboratories,
 - b) up to date records of on site facilities and the purpose they are used for,
 - c) information of on site testing/calibration/sampling undertaken,
 - d) an organisation plan that explains the responsibilities in relation to the permanent laboratory or the organisation on site activities are performed for,
 - e) unambiguous identification of those methods the laboratory is accredited to apply on-site. In calibration unambiguous declaration of range and best measurement capability for on-site activities shall be available,
- 6.3 The staff shall have access to relevant parts of the quality manual, procedures and methods on-site.
 - 6.4 Internal audit shall be performed after the same criteria which apply to the permanent laboratory and with intervals of maximum 1 year.

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7. STAFF

- 7.1 The permanent laboratory shall have procedures for relevant training and qualifications of staff involved in on-site activities.
- 7.2 When supplementary staff assists at on-site activities their work must be monitored by trained staff.
- 7.3 Staff not being an employee of the accredited organisation can not independently perform on-site activities.
- 7.4 If consultants or short time staff is used for on-site activities sufficient monitoring must be performed by qualified staff.

8. EQUIPMENT

- 8.1 Precautions must be taken to safeguard equipment after transportation in order to ensure correct function of equipment. Checklist for equipment used for the activity should be available.
- 8.2 Sufficient control on-site to confirm correct function of equipment shall be performed prior to testing/calibration/sampling. If it is impossible to perform such controls the equipment should be checked prior to and after the use on-site. If the equipment is found to be not fit for the purpose or out of calibration it should not be used and immediately marked as defective and taken out of service.

9. REFERENCE-STANDARDS

- 9.1 If it is necessary to make use of a reference standard on-site safeguarding during transport and on-site to ensure the status of the standard. Environmental factors that might influence the standard shall be known and monitored/recorded.
- 9.2 Standards should be kept under suitable environmental conditions. If it is necessary to store the standards on-site appropriate environmental conditions must be provided for.

10. ENVIRONMENT

- 10.1 The environment where accredited activities take place must not have effect on the validity of the results.
- 10.2 Where environmental factors may affect the precision of the measurements quantitative analyses of the effect shall be made.

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10.3 Good house keeping shall be provided for in the area where on-site activities take place.

10.4 Access to on-site laboratories and its equipment shall be controlled.

11. MEASUREMENT UNCERTAINTY

Measurement uncertainty shall be estimated according to agreed procedures and take into account environmental factors. If possible the laboratory should take part in proficiency testing for on-site activities. If sampling is involved attention must be made to the fact that the contribution from sampling often is larger than the contribution from the testing.

12. SAMPLING

12.1 Sampling should be based on international or national standardized methods due to the fact that is difficult to objectively control the sampling process.

12.2 Precautions must be made to identification, handling, transportation, mounting and storage to avoid exchange, damage or contamination of samples.

13. RECORDS

13.1 A system for records that is fit for purpose must be available and include relevant regulations, original observations, plans, data and copies of reports for a defined detention period of time. Records shall be sufficient to make the laboratory able to reconstruct the activity.

13.2 Procedures that ensure confidentiality in on-site activities shall be implemented.

14. REPORTS/CERTIFICATES

14.1 Besides the general requirements to reports/certificates the following should be included:

- a) It shall be clear which parts of the report that concerns on-site activities,
- b) on-site location, date for the activity and the condition of the sample or other relevant information,
- c) description of the environmental conditions.

15. ACCESS TO ON-SITE ACTIVITIES

15.1 DANAK's assessors and customers shall have access to on-site activities similar to the access to the permanent laboratory. If access to the on-site activities is controlled by a third party the accredited body must negotiate appropriate access to on-site facilities for DANAK's assessors.

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15.2 Assessments on-site is not a substitute to assessments in the permanent laboratory but complimentary to those.

16. ACCREDITATION DOCUMENT

On delimitation of the scope DANAK will clarify which parts of the scope that are performed on-site.

DANAK, 20 June 2001

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