1. Delimitation

This guideline applies to all laboratories which are accredited to calibration, testing and medical examination, according to ISO/IEC 17025 and ISO.15189.

2. Objective

DANAK's Guidelines express DANAK's interpretation of relevant paragraphs in accreditation standards, etc. to ensure a harmonisation of the conditions imposed on accredited laboratories.

This Guideline express DANAK's interpretation on how to insure sufficient competence for the personnel authorized to issue and sign calibration certificates, test reports and results from medical examinations.

3. Definition

Signatory: Person who is authorized by the laboratory management to issue and sign calibration certificates, test reports and reports from medical examination.

4. Authorization

The conditions for authorizing are stated in ISO 17025, section 5.2.5, and ISO 15189, section 5.1.7, and will be highlighted in this guideline. The laboratory authorizes personnel according to internal procedures and the following issues must be handled.
For Laboratories accredited to NDT supplementary guidelines are stated in EA-4/15 Accreditation for Non-Destructive Testing, chapter 4 and 5.

4.1 The training of staff takes the actual skills of every member of staff in account, and compares them to the needed qualifications for authorization in the specific area. This leads to at training programme for authorization.

4.2 The training programme can – depending on the level of authorization- take the starting point in the following issues:

- 4.2.1 Knowledge of the method for calibration, testing and medical examination.
- 4.2.2 Understanding of critical parameters for the calibration- test- or examination- method, including knowledge of the measurement uncertainty.
- 4.2.3 Knowledge for controlling nonconforming testing and/or calibration according to ISO 17025, section 4.9, or nonconforming medical examination according to ISO 15189, section 4.9.
- 4.2.4 Evaluation of validity of a result from a calibration, test or medical examination.
- 4.2.5 Competence for giving statements and interpretations. For laboratories performing medical examinations, in addition competence to provide supplementary or detailed remarks to the referral laboratory's results and findings of examinations, in the context of the patient and the local medical environment.
- 4.2.6 Knowledge of reporting results according to ISO 17025, section 5.10, and ISO 15189, section 5.8.

4.3 The laboratory must keep records for authorized personnel, the records shall contain date of issuing and eventually terminating the authorization. The records shall include contracted personnel. The records must be readily available.

4.4 **Obligation to provide information**:

4.4.1 Laboratories which have not previously performed the authorization of personnel for issuing calibration certificates, test reports or reports from medical examination, must provide DANAK with the necessary documentation for the authorization process before the authorization can be initiated.

4.4.2 Surveillance of trainees and authorization to issue calibration certificates, test reports or reports from medical examination are key functions. If the laboratory due to lack of staff members is not able to fulfil these key functions, DANAK must bee informed immediately according to TF 4, § 7, no.1.

4.4.3 DANAK must before every surveillance visit to the laboratory receive the actual record for authorized personnel for issuing calibration certificates, test reports or results from medical examinations according to TF 4, § 3.

4.4.4 If the laboratory due to lack of staff members is not able to issue calibration certificates, test reports or results from medical examinations , and thereby must reduce the accredited scope for a period, DANAK must be informed according to TF 4, § 7, nr. 3.

5. References

5.1 DS/EN ISO/IEC 17025:2005: General Requirements for the competence of testing and calibration laboratories.

5.2 DS/EN ISO 15189:2005: Medical laboratories – Particular requirements for quality and competence.

5.3 Technical regulation no. 4 Rules concerning the obligation to provide information, 2006 (TF 4).

5.4 EA-04/15 Accreditation for Non-Destructive Testing, 2003.

6. Amendments

None.

7. Coming into force.

This Guideline, which supersedes the previous version of 2000.06.15, comes into force on march 24th 2007. Personnel who have been authorized by DANAK as signatories according to the previous guideline RL 12 will not need to participate in training programmes within the authorized area, when this guideline comes into force.

DANAK, January 18th. 2007

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