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| **Accreditation no.:** «Akknr» | **Type of visit:** visit |
| **Company/laboratory and (if rel.) department:** «Labnavn1» | **Technical assessor:** |
| **Address(es):** «Labadresser» | **Report date:** 27 May 2020 |
| **Dato(s) of visit:** |  |

# Horisontal audit – DS/EN ISO/IEC 17025:2017

***Resources***

(Clauses refer to ISO 17025:2017 and to AB’s where relevant)

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| **6.2 Personnel** | |
| There are extra requirements in 6.2.5 on procedures compared to the 2005 edition | |
| **6.2.2** | |
| Documentation of competence requirements | |
| **6.2.5 f)** | |
| Procedures for monitoring competence of personnel | |
| **Employment, training and education** | |
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| **Job descriptions and authorizations** | |
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| **Staff member** | **Assessment of records regarding competence, training etc.** |
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| **Flexible scope** |
| Competence of staff to validation and verification under flexible scope is assessed under this item.  TA should assess the competence to perform validation of authorised staff members, the procedures for validation/verification and examples of validations/verifications within the flexible scope according to the requirements in AB 10 section 5. |

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| **6.3 Facilities and environmental conditions** | |
| Unchanged requirements | |
| **Facility/room** | **Assessment of requirements, records etc.** |
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| **6.4 Equipment and 6.5 Metrological traceability** | |
| Substantial change in the definition of ”equipment”. Now includes software, firmware, reference materials and reagents  Hence several clauses from the 2005 edition are ”fused” (5.5+5.6)  6.4.13 f) concerning documentation for period of validity for RM is new  Requirements for traceability is identical to ILAC P10 and the requirements in AB3, which implements P10  6.5.2 c) is only relevant if the lab realises SI units and in such case must participate in relevant laboratory comparisons, cf. AML K04 | |
| **Equipment (or RM)** | **Assessment of records regarding maintenance and calibration etc.** |
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***Processes***

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| **7.2 and 7.6 Selection, verification and validation methods and evaluation of measurement uncertainty**  AB 11, 12 and 13 (concerning uncertainty), AB 10 (concerning flexible scope) | | |
| Assessment that relevant requirements for verification (7.2.1) are always met. Requirements for validation (7.2.2) are only necessary for methods that require validation.  In accordance with 7.6.1 uncertainty contributions from sampling must be taken into account when possible. | | |
| **Demonstrated competence**  Test/calibration demonstration and/or interview of staff | | |
| **Method/procedure** | **Staff member(s)** | **Assessment (may include sampling cf. 7.3 and handling cf. 7.4)** |
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| **List of methods and/or measurement scheme** |
| Measurement capabilities: Assess whether AML K04 concerning high metrological level is relevant, whether the sorting of lines is suitable and that a suitable reference to the method is given, cf. AML 18.  List of methods: Are suitable test items specified (or are new items necessary), the measurement principle (where relevant), identification of own method and reference method given with title and year (e.g. EN or ISO methods). Is the sorting suitable and other requirements of AML 18? |

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| **7.3 Sampling (see also 7.2 and 7.6)** |
| Clause 5.7.2 is gone concerning changes to sampling procedures. Refer to contract review  7.3.3 is more specific (“where necessary”). 7.8.5 f) concerning reporting. |

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| **7.4 Handling of test or calibration items (see also 7.2 and 7.6)** |
| Unchanged |

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| **7.7 Ensuring the validity of results**  AB 3, section 3 (concerning proficiency testing), Reference to PT by assessment of new methods is specified under section 5.4. | |
| More options mentioned | |
| **Internal quality assurance of results (cf. 7.7.1)** | Must be filled – especially if some of the new possibilities for internal quality control are used, items a) to k). |
| **Procedures for external quality assurance (PT)** |  |
| **Plans for PT and covering of scope** |  |
| **Resultats from participation in PT** |  |

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| **7.8 Reporting of results**  AB 3, section 5. Use of DANAK’s accreditation mark, cf. AB 2. | | | |
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| **7.8.2.2** | | | |
| Specification of results are on items as received and identification of and disclaimer concerning data provided by the customer | | | |
| **7.8.6** | | | |
| Statements of conformity and decision rules | | | |
| **7.8.7** | | | |
| Concerning communication with the client regarding opinions and interpretations | | | |
| **7.8.8.1** | | | |
| Amendments to reports | | | |
| **Report no.** | **Staff member** | **Method/Standard** | **Remarks/assessment** |
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| **7.11 Control of data and information management** |
| This is a new clause and should be assessed completely |

# Vertical audit

**Going through of file**

Going through of file(s) or other activity in laboratory

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| **File/activity** | **Assessment** |
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# Horisontal audit

(Other reporting)

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# Conclusion

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| Statement on recommendation |