|  |  |
| --- | --- |
| **Accreditation number:** | **Type of visit:**  |
| **Company/laboratory (and if relevant department):** | **Technical assessor:**  |
| **Address(es):** | **Report date:**  |
| **Date(s) of visit:**  |

# Horisontal audit – DS/EN ISO 15189

(Sections refer to DS/EN ISO 15189 and accreditation regulation (AB) where relevant)

*Red text prompts are for orientation purposes only and to be deleted “after use”.*

***Technical requirements***

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| **5.1 Personnel** |
|  |
| **Introduction, training and education plus assessment of competence and performance**  |
|  |
| **Job descriptions and authorizations** |
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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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| **5.2 Accommodation and environmental conditions** |
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| **5.3 Laboratory equipment, reagents, and consumables**  |
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| --- |
| **5.4 Pre-examination processes**  |
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| --- |
| **5.5 Examination processes**AB 10 (concerning flexible scope) |
|  |
| **Demonstrated competence**Demonstration of method and/or interview of staff member(s) |
| **Method/procedure** | **Staff member(s)** | **Assessment** |
|  |  |  |
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| --- |
| **List of methods**  |
| *Are e.g. methods and equipment/principle correctly specified and is sorting according to AML 18.* |

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| --- |
| **5.6 Ensuring quality of examination results**AB 3 section 3 (concerning proficiency testing). Reference to PT by assessment of new methods is specified under section 5.5 |
|  |
| **Policy and procedures for PT** |  |
| **Plans for PT and covering of scope** |  |
| **Results from participation in PT** |  |
| **Other quality assurance of results** |  |

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| **5.7 Post-examination processes**  |
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| **5.8 Reporting of results**AB 3 section 5 and use of DANAK’s accreditation mark cf. AB 2 |
|  |
| **Report no./result id.** | **Remarks/assessment** |
|  |  |
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| **5.9 Release of results** |
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| **5.10 Laboratory information management** |
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# Horisontal audit – other

(Other reporting relevant for e.g. chapter 4 in DS/EN ISO 15189, accreditation regulations etc.)

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# Vertical audit

**Going through a file**

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

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| --- | --- |
| **File/activity** | **Assessment** |
|  |  |
|  |  |

# Conclusion

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| *If relevant, conclusions regarding extensions/approvals* |