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| --- | --- | --- | --- | --- |
| **Details of the conformity assessment body (CAB)** | | | | |
| Name: |  | | | |
| File number: |  |  | |  |
| Case number | Phase | |  |
| Date of assessment: | Please select | | | |
| Accreditation process: | Please select | | | |
| Assessment type[[1]](#footnote-1) : |  | | | |
| CAB with several locations: | | Yes | No | |
| Name / Address of assessed locations: | |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Details of the assessor** | | | |
| Name: |  | | |
| Status[[2]](#footnote-2) : | SA | TA | TE |

|  |
| --- |
| **Statement to the flexible scope of accreditation:** |
| The testing, calibration or examination areas and categories of the flexible scope correspond to the draft agreed upon before the assessment or the currently valid annex to the accreditation certificate. |
| **Yes,** Please select continues to apply. |
| **No,** Please select will be submitted with marked changes with this report/checklist to the DAkkS. |

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| **The laboratory maintains at the time of the assessment a current list of all testing, calibration or examination methods covered by accreditation. (including an identification of the last changes):** |
| **Yes** Date of issue of the list:Please select |
| **No** (A corresponding non-conformity will be set in a non-conformity-report and in the partial assessment report.) |

|  |
| --- |
| **Introduced and applied methods within the scope of accreditation since the last assessment:** |
| Standard test methods or their equivalent (category I). |
| Modified, new introduced or developed test methods (category II). |

This checklist is used to evaluate fulfillments of requirements regarding accreditations with a flexible scope   
of category I and II.

The evaluation of the fulfillment regarding requirements of category III is not subject of this form, but will be documented within the checklist/partial assessment report FO-B\_PL\_17025-2018\_EN or FO-B\_ML\_15189-2014\_EN.

In addition to the report for testing laboratories according to ISO/IEC 17025:2018 and for medical laboratories according to ISO 15189:2014 this checklist references the detailed requirements to the laboratories, which have applied for a flexible scope of accreditation or which are already accredited with a flexible scope of application. The checklist only contains requirements which are especially to be considered for the implementation of a flexible scope (category I or II).

This checklist/this report does NOT repeat the objective evidence (OE) and reviewed documents (RD), text passages and explanation of non-conformities listed or given in the partial assessment report according to ISO/IEC 17025 or ISO 15189. The responsible assessor MAY, however, list further documents and add explanatory text. Non-conformities arising from the application of this checklist have to be documented in the partial assessment report/ checklist.

Note: The ***italic, bold, and blue formatted passages*** refer to the ***requirements of ISO 15189***.

| **No. [[3]](#footnote-3)** | **Implementation of the requirements in relation to the flexible scope of accreditation** | **Fulfilled** | **Not fulfilled** | **Notes  (optional) [[4]](#footnote-4)** |
| --- | --- | --- | --- | --- |
| 6.2.2 ***5.1*** | Are competence requirements determined for personnel who should be authorized or are authorized to modify or develop, to verify or validate test methods / ***examination methods***? |  |  |  |
| 6.2.6 ***4.1*** | Are **responsibilities** regarding the modification or new development of test methods / ***examination methods*** documented as well as for validation or verification (personnel authorized)? |  |  |  |
| 7.2 ***4.2.1*** | Are **procedures** of the laboratory for the implementation of new or modified test methods / ***examination methods*** within the management system considered and documented with necessary extent? |  |  |  |
| 8.4 ***4.13*** | Are modifications of test methods / ***examination methods*** or development activities **recorded** completely including all underlying results of the validation and verification as well as other relevant data? |  |  |  |
| 8.8 ***4.14*** | Is the process regarding the implementation of new or modified test methods / ***examination methods*** considered within the **audit programme**? |  |  |  |
| 8.9 ***4.15*** | Will the process regarding the implementation of new or modified test methods / ***examination methods*** be considered as part of **management reviews**?  (suitability and effectiveness of the management system regarding the control of the flexible scope of the accreditation including the evaluation of basics on which new, modified and/or current test methods / ***examination methods*** will be released and the competence of the personnel authorized for this; see 6.2.5.f) |  |  |  |
| 7.2 ***5.5*** | Are verified and/or validated **test methods** / ***examination methods*** applied within the defined limits in the flexible scope of the accreditation? |  |  |  |
| 7.7 ***5.6*** | For ensuring the validity of results, is the development, evaluation, validation and release of new and modified test methods / ***examination methods*** with regularly appropriate measures examined?  (Results of Internal or external quality controls are to be considered. Recordings about these activities must be available to DAkkS.) |  |  |  |
| EA-2/15 M | Does the CAB maintain a list of accredited activities conducted under its flexible scope and is it publicly available? |  |  |  |

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| --- | --- | --- | --- | --- | --- |
| Place |  | Date | Please select | Signed *Name Assessor*[[5]](#footnote-5) |  |

1. Under assessment type, the assessment technique is to be indicated, whereby several assessment types can be used in the context of an assessment. Please select the applicable element or combination of elements from the following options to indicate the type of assessment:   
   On-site assessment / Remote assessment / Witness audit (on-site) / Witness audit (remote) / Witness examination /   
   Document review / Other assessment activity (please specify if necessary) [↑](#footnote-ref-1)
2. Status in the assessment team: SA = System Assessor; TA = Technical Assessor; TE = Technical expert [↑](#footnote-ref-2)
3. For the check of the individual standard clauses the assessors mentioned in the partial assessment report are responsible. [↑](#footnote-ref-3)
4. Here can be referenced to the appropriate section of the partial assessment report. [↑](#footnote-ref-4)
5. This report/checklist has been electronically compiled by on Please select and is valid without signature. [↑](#footnote-ref-5)