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

|  |  |  |
| --- | --- | --- |
| **Details of the assessor** | | |
| Name: |  | |
| Status: | System Assessor | Technical Assessor |

|  |
| --- |
| **Since the last assessment, the following have been introduced and applied within the scope of accreditation:** |
| Standardized and/or equivalent examination methods (category I) |
| Modified, new or/and further developed examination methods (category II) |

This checklist is used to evaluate the fulfilment of the requirements for accreditations with flexible scope of category I and II.

In addition to the report for medical laboratories, this checklist covers the detailed requirements for laboratories that have applied for a flexible scope accreditation or have already received an accreditation with a flexible scope. The checklist only contains those requirements that must be taken into particular consideration for the application of a flexible scope of accreditation (Cat. I and II)

This checklist does NOT repeat the objective evidence (OE) and reviewed documents (RD) or text passages and descriptions of non-conformities already listed in the DIN EN ISO 15189 report. However, the responsible assessor **may** reference supplementary documents and make comments. For unfulfilled requirements resulting from the application of this checklist, corresponding non-conformities are referenced in the partial assessment report.

Note: The sections of the standard formatted in ***color*** in the table below refer to the requirements of   
***DIN EN*** ***ISO 15189:2014 (blue)*** and ***DIN EN ISO 15189:2023 (red) or DIN EN ISO 15189:2024 (red)***.

| **Norm-punkt [[2]](#footnote-2)** | **Umsetzung der Anforderungen  in Bezug zum flexiblen Akkreditierungsbereich** | | | | | **Fulfilled** | **Not fulfilled** | **Notes  (optional) [[3]](#footnote-3)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***5.1***  ***6.2.2*** | Are **competence requirements** determined for personnel who are authorized to modify or develop, to verify or validate examination methods? | | | | |  |  |  |
| ***4.1***  ***6.2.3*** | Are **responsibilities** for the modification or new development of examination methods and validation or verification documented (authorization granted)? | | | | |  |  |  |
| ***4.2.1***  ***7.3*** | Are the laboratory's **procedures** for the introduction of new or modified examination methods considered in the management system and documented to the required extent? | | | | |  |  |  |
| ***4.13***  ***8.4*** | Are modifications to examination methods or development activities, including all underlying validation and verification results and other relevant data, fully **recorded**? | | | | |  |  |  |
| ***4.14***  ***8.8*** | Is the process for implementing new or modified examination methods considered in the **audit programme**? | | | | |  |  |  |
| ***4.15***  ***8.9*** | Is the process for incorporating new or modified examination methods considered as input to the **management review**? | | | | |  |  |  |
| ***5.5***  ***7.3*** | Are **verified** and/or **validated** examination methods applied within the limits specified in the flexible scope of accreditation? | | | | |  |  |  |
| ***5.6***  ***7.3*** | Is the development, evaluation, validation and approval of new or modified examination methods regularly documented with suitable measures to **ensure the validity** of the results? | | | | |  |  |  |
| EA-2/15 M | Does the laboratory maintain a **publicly available list** of accredited activities performed within its flexible scope? | | | | |  |  |  |
| List status: |  | Is this published list up to date? | | |  |  |  |
| Does this list of all examination methods within the (flexible) scope of accreditation contain at least the following information for each examination method?  - Analyte,  - Examination material,  - Examination technique,  - Procedure incl. version  - Reference to the examination field in the annex of the DAkkS accreditation certificate | | | | |  |  |  |
| Are the limits of the flexible scope complied with? | | | | |  |  |  |
| Reference of the publication: | | | | | | | |
| Website of the laboratory | | | Web-Address: |  | | | | |
| Official journal | | | Reference: |  | | | | |
| Others: | | | Explanation: |  | | | | |

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| --- | --- | --- | --- | --- | --- |
| Place: |  | Date: | Please select | Signed *Name Assessor*[[4]](#footnote-4) |  |

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. For the check of the individual standard clauses the assessors mentioned in the partial assessment report are responsible. [↑](#footnote-ref-2)
3. Here can be referenced to the appropriate section of the partial assessment report. [↑](#footnote-ref-3)
4. This report/checklist has been electronically compiled by on Please select and is valid without signature. [↑](#footnote-ref-4)