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| |  |  |  |  | | --- | --- | --- | --- | | logo SNAS |  | **Checklist for testing, calibrationand and medical laboratories**  **with FLEXIBLE SCOPE** | | |  |  | **Registered member No:** | **Service number:** | |  |  | **Certificate No:** |  | |  |  |
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| |  |  |  |  | | --- | --- | --- | --- | | **No.** | **Question / Note** | **Fill up** | | |  |  | **Yes** | **No** | | **1** | Does the laboratory have documented system for control of the flexible scope (FS) and actualization of the „List of activities conducted under the flexible scope“ („List“)? |  |  | |  |  |  |  | | **2** | Are the responsibilities of the management established for FS including responsibilities for all activities covered by flexible scope and actualization of the „List“? |  |  | |  |  |  |  | | **3** | Does the laboratory have documented detailed information on what is/can be covered by accredited FR in its system? |  |  | |  |  |  |  | | **3.1** | Is this information understandable, transparent and available for all interested parties? |  |  | |  |  |  |  | | **4** | Does the laboratory have publicly available "List" for all interested parties? |  |  | |  |  |  |  | | **5** | Does the laboratory have suitably qualified personnel for the validation or verification of activities covered by FS? |  |  | |  |  |  |  | | **5.1** | Are the evidences available about the competence of personnel and about their trainings? |  |  | |  |  |  |  | | **6** | Does the laboratory have documented procedures for validation or verification activities covered by FS? |  |  | |  |  |  |  | | **6.1** | Are the records available of these activities? |  |  | |  |  |  |  | | **7** | Does the laboratory, which is competent to develop new methods, have documented procedures for development and validation of new methods covered by FS? |  |  | |  |  |  |  | | **7.1** | Are the records available of these activities? |  |  | |  |  |  |  | | **8** | Is the metrological traceability ensured (where applicable) for established new activities in according to the relevant SNAS policy? |  |  | |  |  |  |  | | **9** | Are all necessary documents concerning the new, additional or modified activities available at all locations where the activities are performed? |  |  | |  |  |  |  | | **10** | Are the already performed activities not negatively influenced by newly implemented, additional or modified activities? |  |  | |  |  |  |  | | **11** | Are all activities linked with establishing of new, additional or modified activities and with their execution assured so to minimize the risk of defective performance of accredited activities? |  |  | |  |  |  |  | | **12** | Does the laboratory have documented procedure for receipt of an application for activities under the accredited FS that have not been carried out yet? |  |  | |  |  |  |  | | **12.1** | In the case the laboratory accepted such application did it have the access to all necessary resources required for the completion of the requested activity? |  |  | |  |  |  |  | | **13** | Does the laboratory inform its clients about procedures for including requested activities in its „List“ before they were carried out? |  |  | |  |  |  |  | | **14** | Does the laboratory inform its clients that it will not be able to issue accredited results unless all the requested activities are satisfactorily accomplished? |  |  | |  |  |  |  | | **15** | Does the laboratory inform its clients about the facts related to the FS which influence price for performed service and turnaround time? |  |  | |  |  |  |  | | **16** | Does the laboratory inform its clients of problems which hinder from accomplishing the offered service successfully linked with FS (if that situations is actual)? |  |  | |  |  |  |  | | **16.1** | Does the laboratory adopt such corrective action and in consequence such preventive action in the case of problems appearance, in order to resolve the problem identified and to ensure it does not happen again in the future? |  |  | |  |  |  |  | | **17** | Are the evidences available about updating of the „List“ after performing the required activities? |  |  | |  |  |  |  | | **18** | Is it available evidence about approval of addition of the additional activities to the „List“? |  |  | |  |  |  |  | | **19** | Did the laboratory inform SNAS about performing of every change in the „List“? |  |  | |  |  |  |  | | **20** | Did the laboratory redefine boundaries, within which the scope is flexible, in cooperation with SNAS, if the problem with the possibility to offer the services in the accredited FS is still actual? |  |  | |  |  |  |  | | **21** | Does CAB understand the rules and procedures for the implementation and management of FR? |  |  | |  |  |  |  | | **22** | Is the performance and stability of management system of CAB sufficient? |  |  | |  |  |  |  | | **23** | Does CAB in FR consider the complexity of conformity assessment activities? (for example, with new and emerging activities, the competency requirements may not yet be fully known) |  |  | |  |  |  |  | | **24** | Is the scope of flexibility provided by CAB satisfactory? |  |  | |  |  |  |  | | **25** | Does CAB consider risks in the performance of the activities carried out within the framework of flexibility? |  |  | |  |  |  |  | | **26** | Is the stability of the professional personnel within CAB responsible for activities related to the flexible scope sufficient? |  |  | |  |  |  |  | | **27** | Is the flexible scope used to meet regulatory authority requirements? |  |  | |  |  |  |  | | **28** | How frequently is the list updated? |  |  | |  |  |  |  | | **29** | Is the scope of controls suggested by the CAB suitable to manage the flexible scope? |  |  | |  |  |  |  | | **29.1** | Are available proofs of the performance of controls implemented by the CAB for managing a flexible scope? |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | |  |
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| |  | | --- | | Laboratory with flexible scope | | Notes:  (List of checked records about performed validations or verifications within the FS)  (By surveillance - list of checked records about performed new validations or verifications within the FS) | |  | | Laboratory with flexible scope, which is competent to develop new methods | | Notes:  (List of checked records about development of new methods and their validation within the FS)  (By surveillance – list of checked records about development of new methods and their validation within the FS) | |  | | |  |