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| Logo SNAS |  | |  | | --- | | Checklist for testing, calibration and medical laboratories  with FLEXIBLE SCOPE | | | |  |  |
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|  |  |  |  | |  | | --- | | Service number: | | |  |
| |  | | --- | | No registered member: | | | |  |  |
|  |  |  |  |
| |  | | --- | | 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 the final user? |  |  | |  |  |  |  | | **4** | Is the „List“ available publicly to the final users, interested parties and accreditation body? |  |  | |  |  |  |  | | **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** | Does the laboratory have elaborated procedure for metrological assurance of the new activities which have not been carried out yet? |  |  | |  |  |  |  | | **8.1** | Is the metrological traceability ensured for established new activities in according to the relevant SNAS policy? |  |  | |  |  |  |  | | **9** | Are all necessary documents concerning the new activities available at all locations where the activities are performed? |  |  | |  |  |  |  | | **10** | Is it possible to state that new established activities do not influence negatively activities that have been already carried out? |  |  | |  |  |  |  | | **11** | Are all activities linked with establishing of new 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 the authorization 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? |  |  | |  |  |  |  | | 24 | Is the scope of flexibility provided by CAB satisfactory? |  |  | |  |  |  |  | | 25 | What are the risks to the reputation of SNAS, CAB and the market? Does CAB consider these 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 knowledge of CAB personnel sufficient to confirm compliance between the relevant standards and the activities performed in CAB? |  |  | |  |  |  |  | | 28 | Is the flexible scope used to meet regulatory authority requirements? |  |  | |  |  |  |  | | 29 | Is the planned frequency of using the flexible scope sufficient? |  |  | |  |  |  |  | | 30 | Is the scope of controls suggested by the CAB sufficient to manage the flexible scope? |  |  | |  |  |  |  | | 31 | Has CAB considered the location and geographical risks in the performance of activities included in the FR? |  |  | |  |  |  |  | | | | | | |  |
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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) | |  | | | | | | |  |
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