R20.03

Revision No : *03*
Effective Date : *30.11.2023*

Declaration of the Scope to be Accredited for Medical and Testing Laboratories

1. PURPOSE AND SCOPE

This Guide covers identification regarding studies constituting the basis of accredited scope of medical/testing laboratories and declaration of such studies to the Turkish Accreditation Agency (TURKAK).

In accreditation applications, the accredited scopes can be accessed from the scope catalogs created on the TÜRKAK portal. Scope catalogs can be accessed under the Accreditation/Scope heading at portal.turkak.org.tr.

For scopes that are not included in the scope catalog, an out-of-catalogue scope request is made. When making scope requests for tests that are not included in the scope catalogue, the rules given in the second section should be taken as basis.

2. PARAMETERS ABOUT THE SCOPE TO BE ACCREDITED

1. Medical examination (analysis)/testing field requested to be accredited shall be defined clearly (for example: electrical products, microbiology, mechanical, ...etc.).
2. Products subject to medical examination (analysis)/testing shall be defined in general or specifically (for example: **water, wastewater, paints, food, meat and meat products**, safety belt, polymer materials, metal and metal alloys, whole blood, urine.....etc.).
3. Medical examination (analysis)/testing applied shall be explained by giving the information below.
    - measurand quantities/properties measured (for example: **quantification, temperature determination**, electrochemical testing, blood cell count, tension, elemental composition of substances, tensile stress,.....etc.).
    - measurement range **(where applicable).**
    - uncertainties that arise (where applicable).
    - product standards, testing method standards applied.

4. Medical examination (analysis)/testing methods and procedures used shall be defined in general or specifically. These can be standardized methods or non-standard (in-house) methods.
   - Non-standard methods or in-house methods are the methods developed by the laboratory or a third party or the methods validated by being adapted from standard methods.
   - Standard methods are the methods developed by a standardization body or an organization with expertise in its field and adopted and used by the relevant sector.
   - **In cases where the standards within the scope of accreditation do not contain any date information, the current versions of the relevant standards are valid. The general expectation of the Turkish Accreditation Agency is that organizations prepare for assessments by carrying out their work according to the most up-to-date versions of the standards included in their accreditation scope, and refer to the most up-to-date versions of the standard information included in the accreditation scope published following the assessments. There are also special cases regarding this TÜRKAK policy, and the issues expected to be applied for different situations are stated on the TÜRKAK website under the decision texts (Decision Concerning the Currentness of the Standards Included in the Scope of Accreditation).**
5. The scope requested to be accredited shall be presented with a sufficient level of precision. For that purpose, related testing equipment and methods can also be specified.
6. For medical laboratories “Initial Sampling” shall be specified in the application.

3. COMMENTS

Medical examination (analysis) or testing laboratories can update and modify the general methods and procedures it applies in a way that does not cause significant deviation from its accredited scope.

Due to **technological developments, changes in customers’ demands** or the revision of the medical examination (analysis)/ testing standards, the laboratory may need to use the new method standard that comes into force.

If new, revised or upgraded medical examination (analysis) or testing methods do not include measurement principles that **have not been previously covered within the scope of accreditation, this change must be notified to TURKAK**. As a result of the evaluation, an application for scope extension and a technical assessment obligation may arise. Furthermore, the reports prepared shall include the standard/instruction with its effective date used for the medical examination (analysis)/testing method applied.