

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 NBE-New Business Education Foundation.

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: 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: electrochemical testing, blood cell count, tension, elemental composition of substances, tensile stress, etc.).
 - measurement range.
 - 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.
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 they apply depending on technological developments or due to changes in clients' requests in a way not to result in any significant deviation from their accredited scope and on the condition of notifying NBE about such updates and modifications.

Due to the revision of the medical examination (analysis)/ testing standards, the new method standard which has come into force can be used by the laboratory. However, new, revised or upgraded medical examination (analysis) or testing methods shall not include measurement principles that have not been addressed previously within the scope of accreditation. Otherwise, it will be obligatory to make an application for extension of scope and subsequent technical assessment. Furthermore, the reports prepared shall include the standard/instruction with its effective date used for the medical examination (analysis)/testing method applied.