

INTRODUCTION

This guideline was drawn up to land assistance in determining the optimal time required for the assessment activities to be conducted by assessors and technical experts appointed to carry out the accreditation assessments of Conformity Assessment Bodies.

By using the methods and approaches in this Guideline, it is possible to provide a consistent basis for calculating, by using Man-day unit, the time required to perform the accreditation assessment for the Conformity Assessment Bodies (CAB), which range in size and perform activities in different levels of difficulties.

Calculation of the assessment time, which is an important activity of the preparation period, for the accreditation assessment in Man-day unit should be open to flexibility, as a result of taking the findings emerged during the first phases of the assessment processes.

Determining the time to be allocated

The scope of the activities conducted by an organization should be taken into consideration as the main factors while determining the assessment time on the basis of Man-day regarding the assessment of the Conformity Assessment Body to be assessed in terms of accreditation. The number of personnel participated in conformity assessment activities, organizational structure of the organization, locations on which activities are conducted, and the width and difficulty of the scope are assessed besides the scope of the organization.

In addition to this, it will be necessary to observe by sampling conformity assessment activities, or performing witness assessment by giving priority to the critical certification and inspection works conducted on-site to determine the competence and performance of the Conformity Assessment Body.

Adequate assessment time (Man-day) is determined by the case officer handling with the application file by taking the below-mentioned points into consideration.

The case officer determines the time required for the assessment process by taking all kinds of information and data submitted by the organization into consideration, while establishing an assessment team.

Factors extending the assessment time (Man-day)

- 1) Activity conducted in more than one branch/building and limited transportation–communication potential
- 2) Assessment work requiring translation
- 3) Works required to be performed under high safety precautions
- 4) Assessment performed under land conditions
- 5) Work under the regulating effect of the official regulations
- 6) A great number of CAB personnel and/or a wide scope to be assessed

Factors reducing the assessment time (Man-day)

- 1) The fact that the scope to be accredited has been accredited by another accreditation agency
- 2) The fact that the scope to be assessed and the number of CAB personnel are limited
- 3) Maturity of management system of the applicant organization
- 4) Simplicity of the conformity assessment activity under the scope to be accredited and performance of the same duty by a great number of personnel
- 5) Having been accredited according to another accreditation standard

Assessment time (Man-day) includes file examination, assessment planning, performing the necessary correspondence activities, and assessment and reporting activities conducted by the assessors. On the other hand, the time to be used in direct assessment should not be below 75% of total Man-day level. This percentage should also be taken into consideration in initial accreditation, surveillance and re-accreditation assessments.

Calculated times (Man-day), does not include the time spend by assessors/case officers for transportation.

A Man-day unit corresponds to 8 hours work day. Time (Man-day) should not be reduced by planning a work day longer than 8 hours.

Joint accreditation assessment may be conducted where an integrated system is implemented in accreditation applications for different standards. Accordingly, the Man-day rate for office assessment is found by calculating and adding the number of Man-day rate indicated in the table below. 60 % of the total is reflected.

Below-mentioned times are defined for normal conditions. These times may change with regard to the above-mentioned special conditions.

Points indicated in TABLE 1 are taken into consideration while determining total assessment times (Man-day) of laboratories, management system and personnel certification bodies.

TABLE 1

FOR LABORATORIES	
Location Assessment (location assessment and reporting on document examination, preliminary preparation and quality management system) (Man-day)	Technical Activities (Testing/Calibration Methods) (Man-day)

3±1	<p>2±1 (For each assessor/technical expert)</p> <p>(The number of assessors/case officers is determined by calculating separately for each field in such a manner that it covers Assessment/Calibration fields.)</p>
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Medical laboratories, proficiency testing providers and reference material producers are also considered as laboratories.

FOR PERSONNEL CERTIFICATION BODIES	
<p>Location Assessment (location assessment and reporting on document examination, preliminary preparation and quality management system) (Man-day)</p>	<p>Technical Activities (Personnel Certification Programs) (Man-day)</p>
3±1	<p>2±1 (For each assessor/technical expert)</p> <p>(The number of assessors/case officers is determined by calculating separately for each field in such a manner that it covers Personnel Certification Programs applied.)</p>

FOR MANAGEMENT SYSTEM CERTIFICATION BODIES		
Application scope of the CAB	<p>Location Assessment (location assessment and reporting on document examination, preliminary preparation and quality management system) (total Man-day for each MS, including assessor/technical expert)</p>	Witness Assessment Man-day
1-10	3±1	It is taken into consideration in accordance with the time to be spent in location assessment by the applicant CAB.
11-20	4±1	
21-.....	5±1	

Statements regarding TABLE 1

- 1) Times (Man-day) given in the tables is for the initial accreditation procedures. Time to be allocated for assessments in an accreditation cycle (first and second surveillances and reassessment) is determined upon reviewing the activities of the organization evenly and by taking the changes in

the structure of the organization assessed, matureness of the management system, accreditation scheme, variety of the accreditation scope, number of locations where conformity assessment activity performed and result of risk analysis for each CAB into consideration. Total time (Man-day) of assessments in an accreditation cycle is allocated for the assessments so that the total amount is initial accreditation time indicated in the related tables multiplied by 1.2 to 2. If a scope extension is requested with surveillance/ reassessment, the time is determined in line with the scope. Regarding the surveillance assessments, if the Certification Body has been accredited for more than one Management System Activity, 0,5 or 1 Man-day is added to each Management System in accordance with the scope.

- 2) The initial Accreditation Man-day rate is calculated as follows for the office assessments of more than one certification activities of the certification bodies applied for accreditation in accordance with ISO/IEC 17021-1:
 - a. Man-day rate is calculated for the bodies applied for accreditation directed to ISO 9001 and ISO 14001 certification activities, as follows:
Man-day rate corresponding to the number of applied scopes for ISO 9001 is added to the Man-day rate corresponding to the number of applied scopes for ISO 14001, and 60% is calculated and reflected.
 - b. If the certification body applies for accreditation of ISO 22000 and/or FSSC 22000 certification activities in addition to ISO 9001 and/or ISO 14001 certification activities, 1 Man-day is added for the determined Man-day rate in cases between 1st to 7th categories, and 2 Man-day is added in cases where the category number is above 7 (see NBE G-4-05 for the above-mentioned categories).
 - c. Besides, in cases of applications for accreditation assessment regarding management systems such as ISO 13485, ISO 27001, ISO 50001 and ISO 45001 in addition to the above-mentioned certification activities, 1 Man-day rate is added to the determined man-day rate for each management system.
- 3) In the accreditation applications for solely ISO 22000 certification activities in accordance with ISO/IEC 17021-1 standard, Man-day rate for accreditation assessment in office assessments is calculated as 3 ± 1 (Reasons for increasing and reducing the rate are stated above.).
- 4) In the accreditation applications for solely ISO 13485 certification activities in accordance with ISO/IEC 17021-1 standard, Man-day rate for accreditation assessment in office assessments is calculated as 3 ± 1 . (Reasons for increasing and reducing the rate are stated above.)
- 5) In the accreditation applications for solely ISO 27001 certification activities in accordance with ISO/IEC 17021-1 standard, Man-day rate for accreditation assessment in office assessments is calculated as 3 ± 1 . (Reasons for increasing and reducing the rate are stated above.)
- 6) In the accreditation applications for solely ISO 50001 certification activities in accordance with ISO/IEC 17021-1 standard, Man-day rate for office assessment of initial accreditation is calculated as 3 ± 1 (Reasons for increasing and reducing the rate are stated above.).
- 7) In the accreditation applications for solely ISO 45001 certification activities in accordance with ISO/IEC 17021-1 standard, Man-day rate for office assessment of initial accreditation is calculated

as 3 ± 1 (Reasons for increasing and reducing the rate are stated above).

If the Certification Body is active in more than one branch, the time (Man-day) is determined by taking the scope of the certification and the number of personnel into consideration in accordance with the assessments to be made in the branches and the qualification of the certification activity conducted in a branch.

Calculation of Assessment Times (Man-day) for Laboratory Accreditation Assessments

Scope of activity for which the organization is applying is regarded as the key factor in determining the assessment time regarding the assessment of laboratories to be subject to accreditation assessment. Whether the organization has more than one branches, number of the laboratory personnel, organizational structure, locations where activities are conducted and, also, the extent and difficulty of the scope are evaluated, in addition to the content of the scope of application pertaining to the organization. In order to determine the competency of laboratories, making observations by taking samples from the applied activities or carrying out the assessment by prioritizing the critical laboratory works will be necessary. Furthermore, the assessor samples during the assessments, taking into consideration the testing/calibration methods and the similarity of the materials to be tested and the devices to be calibrated. Information on the sampling procedures is recorded on the assessment report and Site assessment objective evidence registration form (FR-7-01-37). An assessment planning is performed by the case officer, using FR-7-01-53 Surveillance matrix for testing and calibration laboratories and FR-7-01-68 form for medical laboratories, taking into consideration the scope extension issues, if any, during the surveillance assessments, as well as the reports of previous assessors, Proficiency tests and comparison measures and personnel replacement etc.

In the event that laboratories with multiple branches request accreditation according to ISO/IEC 17025 and ISO 15189, their assessments are carried out within the framework of the G-2-09 Guideline on the Accreditation of Testing Laboratories Serving in Groups.

In case of laboratory assessments, the assessment team decides during the assessments on the number of testing/calibration laboratory personnel within the scope of the applied accreditation and on the minimum number of personnel to be subject to competency evaluation depending on the scope of the applied accreditation. Personnel to be observed during the surveillance assessments are selected in such a way that the entire personnel in charge of testing / calibration activities within the scope of the accreditation are included.

Calculation of Assessment Times (Man-day) for the Accreditation Assessment of Inspection Bodies

By using the procedures and approaches mentioned in this guideline, the time needed for making the inspection bodies of various sizes and/or with multiple branches go through an effective accreditation assessment will be able to be calculated in (Man-day) rate.

As the assessment time, a significant procedure of the preparation process for accreditation assessment, is calculated in (Man-day) unit, a flexible approach should be adopted by taking into account the findings obtained at the document examination stage.

Scope of activity for which the organization is applying is regarded as the key factor in determining the assessment time for the assessment of the inspection bodies to be subject to accreditation assessment on the basis of (Man-day) rate. Whether the organization has more than one branches, number of the laboratory personnel, organizational structure, locations where activities are conducted and, also, the extent and difficulty of the scope are evaluated, in addition to the content of the scope of application pertaining to the organization.

Additionally, in order to determine the competency and performance of the inspection body, making observations by taking samples from the inspection activities or carrying out the site assessment by prioritizing the critical inspection works will be necessary. Points specified in TABLE 2 are taken into account while determining the total assessment time in (Man-day) rate.

TABLE 2

INSPECTION BODIES		
Office assessment and reporting with regard to document examination, preliminary preparation and management system (Man-day)	Office Assessment for each Inspection area (Man-day)	Inspection Site Assessment (Man- day)
3±1	2±1	For each inspection scope, calculations will be made by taking into consideration the risk status and potential time of the inspection activity to be conducted

TABLE 2 states the times (Man-day) required to be taken into consideration while calculating during the office assessment as the assessment offer is prepared, according to the number of the application scope of the inspection body.

At each inspection area, site assessment of activities will be held, provided that highly risky inspection activities will rank first. The time to be calculated in site assessment will be calculated according to the activity to be inspected. (For instance, site assessments should be carried out on the hydraulic lift, electric lift, crane, mobile crane and lifting platforms at the initial accreditation assessment of the inspection body which has applied for an accreditation that will involve hydraulic lift, electric lift, crane, mobile crane, tower crane, hoist, forklift, vehicle lifting lift inspections.

Times indicated in TABLE 2 in (Man-day) unit are provided for the initial accreditation assessments. For the surveillance/ reassessments the same approach is valid as explained above for interpretation of TABLE 1.

If scope extension is applied together with surveillance/reassessment, this time should be calculated outside of the time (Man-day) at the surveillance/reassessment, depending on the size

and characteristics of the scope, and added to the time calculated for the surveillance/reassessment.

If the certification bodies, which have made a request for accreditation pursuant to ISO/IEC 17020, have more than one branches, numbers of accreditation Man-day rates for office assessments are calculated as follows;

- Assessments to be held at branches are determined by taking into account the scope of inspection activities held at branch, the number of personnel and the difficulty level of the inspection activity
- All branches of an inspection body operating with multiple branches should be assessed during an accreditation process.

Calculation of Assessment Times for the Accreditation Assessments of Product Certification Bodies in (Man-day) rate

This guideline has been drawn up in order to assist the optimum determination of the time required for assigning assessment activities to the assessors and case officers appointed for the accreditation assessments of Product Certification Bodies.

By using the procedures and approaches mentioned in this guideline, the time needed for making the Product Certification Bodies of various sizes and/or with multiple branches go through an effective accreditation assessment will be able to be calculated in (Man-day) rate.

Scope of activity for which the organization is applying is regarded as the key factor in determining the assessment time for the assessment of the Product Certification Bodies to be subject to accreditation assessment on the basis of (Man-day) rate. Whether the organization represents a certain product or product group, the number of the product groups and whether the certification body has more than one branch, the number of the personnel involved in the certification activities and the organizational structure are taken into consideration while evaluating.

To determine the competency of the Product Certification Body, site assessment including sampling during the activities conducted on site, test, inspection, design assessment, service assessment and initial inspection of the production process or the quality system by sampling certification activities will be necessary. Total assessment time is determined as Man-day unit and the points detailed in TABLE 3 are taken into consideration.

TABLE 3

PRODUCT CERTIFICATION BODIES

Office assessment and reporting with regard to document examination, preliminary preparation and management system (Man-day)	Office Assessment for each Product Group (Man-day)	Witnessed Site Assessment (Man-day)
3±1	2±1	For each product group, calculations will be made by taking into consideration the risk status and potential time of the inspection activity to be conducted.

In TABLE 3, the Man-day rates to be taken into consideration in accordance with the number of applied scopes based on the production group of Product Certification Body while calculating the time of office assessment in course of preparing an assessment offer are showed.

Witnessed assessment activity will be performed during at least one certification activity of a product, within the scope of each product group. Time to be calculated in site assessment will be calculated in accordance with the activity to be certified. Assessment programs regarding this issue will be requested from the certification body, and planning will be done in line with these programs.

In cases where a site assessment process is not performed during the initial accreditation assessment for at least one product regarding the product group, application of which has been done by Production Certification Bodies, the scope related to this product group will be excluded from the accreditation assessment.

The time to be used in direct site and office assessment should not be lower than 75% of total Man-day rate. The above-mentioned rate should be taken into consideration during the initial assessment, surveillance and re-accreditation.

Times, which are showed as Man-day units in the table, is for the initial accreditation assessments. For the surveillance/ reassessments the same approach is valid as explained above for interpretation of TABLE 1.

If a scope extension is applied with surveillance/reassessment, such a time should be calculated apart from the Man-day rate in surveillance/reassessment, by taking the extent and the characteristic of the scope into consideration, and should be added to the time calculated for surveillance/reassessment.

In cases where the certification bodies, which made accreditation applications in line with ISO/IEC 17065, have more than one branches, accreditation Man-day rates for office assessments are calculated as follows:

- Assessments to be held in the branches are determined by taking the scopes of the certification activities to be performed in a branch, the number of personnel, and risk level of the certification activities performed into consideration.
- All branches of a certification body operating with multiple branches should be assessed under one accreditation process.

Calculation of Times (Man-day) to be Added to Assessment Times for the Assessments of Accreditation for Notification Purposes

TABLE 4

FOR THE ASSESSMENTS OF ACCREDITATION FOR NOTIFICATION PURPOSES	
Office Assessment for each Regulation/Directive (Man-day)	Witnessed Site Assessment for Regulation/Directive (Man-day)
2±1	For each scope, calculations will be made by taking into consideration the risk status and potential time of the conformity assessment activity to be conducted.

Calculation of Assessment Times for the Accreditation Assessments of GHG Verifiers (Man-day)

In NBE assessments, while organizing the office and witness assessments of GHG Verifiers, below stated issues shall be considered by case officer and team leader;

- a. Experience and the maturity of the management system of verification body in terms of GHG Monitoring and Reporting Systems,
 - b. Application scope and number of activity groups
 - c. Number of branches of verification body,
 - d. Number of clients of verification body,
 - e. Number of staff – verifiers and technical experts
 - f. Verification activities in other countries
 - g. Tiers and complexity of operator’s emissions, (combination of clients such as low, medium and high emitters or the types and number of GHG sources and source streams, sizes of the sites etc.)
 - h. Operators with standard and/or non-standard fuel
 - i. Complexity of monitoring plan
 - j. Monitoring methodology
 - k. Operators with continuous measurement methodology
- Man-days of onsite assessments are determined as stated below.

Office assessment: Duration of office assessment is determined according to above stated criteria and results of document review. Criteria to be used for the determination of duration according to the numbers of the clients of Verification Body are stated in NBE G-4-10 Accreditation of GHG Verification Bodies Article 4.1.4. For initial assessment, in any case, minimum office assessment duration is 2 Man-day.

Witness assessment (office part): Assessment stage at which whole internal verification documentation for each selected activity is assessed for witness assessments.

Witness assessment (client site): On site assessment of records of internal verification documents in the operator’s site selected for each activity’s witness assessment. Assessment Man-day is planned considering at least 1 Man-day for each witness activity and according to minimum

durations in the relevant legislation.

TABLE 5

MAN-DAYS FOR THE ACCREDITATION ASSESSMENTS OF GHG VERIFIERS	
Office Assessment	Witness Assessments (client site)
2 Man-day (at least for initial accreditation)	For each witness activity 1 day ⁽¹⁾

⁽¹⁾ The Man-days of witness assessments are determined according to criteria set in NBE G-4-10 Accreditation of GHG Verification Bodies Articles 4.1.4-4.1.6. Man-day of the witness assessment that is performed in the operator's site is determined according to number of assessment team designated as per above stated criteria.