



D05-02

ASSESSMENT

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1 PURPOSE

The purpose of this document is to lay down in detail the assessment procedure and the related tasks or responsibilities of assessor team members. Guidance for the work of assessors and the principles to be followed by them are provided.

This document deals with the general contents applying to all accreditation fields; in addition to them, the assessor team members shall consider in their work the annexes hereto issued separately for each field of accreditation, including:

D05-02d1, Assessment of testing laboratories

D05-02d2, Assessment of calibration laboratories

D05-02d3, Assessment of inspection bodies

D05-02d4, Assessment of certification bodies

D05-02d5, Assessment of environmental verifiers

D05-02d6, Assessment of validation/verification bodies

D05-02d7, Assessment of CABs for notification purposes

D05-02d8, Assessment of medical laboratories

D05-02d9, Remote assessment

2 GENERAL

Assessment is the key step in accreditation procedure, consisting of three basic stages, regardless of the type of auditee (laboratory, certification body, inspection body, verifier):

- Pre-assessment activities,
- Assessment visit on the site,
- Post-assessment activities.

In particular cases, assessment may be carried out without visiting the client's site, in compliance with the provisions from S03, just by examining the documentation and/or by remote assessment.

Through assessment, SA shall make an overall estimate of a client's or an accredited CAB's competence against the requirements of standards and other requirements for accreditation.

Assessment shall be carried out by an assessor team.

3 TASKS AND RESPONSIBILITIES

Assessment shall be carried out by an assessor team consisting of one or more than one assessor/expert.

Lead assessor shall:

- assess the CAB's organisation as well as the integrity and efficiency of its management system;
- conduct the assessment visit and provide information on implementation of the assessment;
- co-ordinate the work of the assessor team.

Technical assessor shall:

- assess professional/technical competence in the particular technical field;
- professionally assess system solutions for adequacy and efficiency.

Expert shall:

- provide professional help and carry out assessments in cooperation with the technical or lead assessor in the particular technical field.

Assessors shall be responsible for providing an objective estimate of fulfilment of accreditation requirements. They shall perform their work in accordance with the rules of the profession, with the responsibilities of good professionals, independently and impartially. Assessors shall notify the coordinator of the existence of any relationships with the CAB under assessment, highlighting in particular the circumstances that could affect their impartiality in carrying out the assessment they are assigned to.

No-one from among the assessor team members shall be allowed to give advice or to exert, in any other way, influence on the auditee, as this might compromise the accreditation procedure and the decision to grant or maintain accreditation. This principle must be complied with throughout the assessment procedure (before, during, and after the assessment visit), as well as outside the assessment. Special attention in this respect is necessary when providing feedback to the auditee, reporting of findings and agreeing on proposals of actions.

Exchange of information between the assessors and the auditee before and after an assessment visit at the client's site, shall take place only through the intermediary of SA, i.e., through the coordinator. Normally, there shall be no direct contacts between the assessors and the auditee. Should there be any direct contacts necessary, SA must be informed to that effect and should agree thereto.

When assessing, the assessors shall respect the confidentiality principle, and shall promptly advise the auditee to that effect at each assessment visit. All the data from the accreditation process shall be considered as confidential, except the accreditation certificate and the annex to accreditation certificate, which specifies the scope of accreditation, and the exceptions specified by the rules in S03.

They shall also respect the rules of protection of intellectual property of the auditee or his customers. Assessment shall follow the principles of correctness and tactfulness. Assessors shall endeavour for mutual respect and trust between them and the representatives of the auditee.

4 GENERAL INSTRUCTIONS FOR ASSESSMENT

The assessor shall obtain substantial evidence of fulfilment (or non-fulfilment) of the requirements wherever possible and acquire sufficient information to be able to make a professional decision.

In carrying out assessments, the assessors shall, along with the requirements for competence (from the normative documents listed in S03), also take into consideration the interpretative documents and guides (listed in D05–10). Technical assessors shall be additionally familiar with any general or specific guides and codes of good practice applicable to their respective technical fields, and shall consider them during assessment as interpretation of requirements for accreditation (e.g., other standards, guides of professional organisations and associations).

Usually, the assessors shall take the solutions from the guides into consideration as possible but not mandatory to meeting the requirements of the standard, which is not mandatory, allowing for the auditee to meet the requirements by other solutions, if he can provide evidence of an equivalent result.

When carrying out an assessment, the assessor team shall assess, in addition to the competence of the client, also his fulfilment of the requirements deriving from SA's internal regulations, which relate to accreditation procedure, e.g., informing SA of essential changes in the accredited CAB (S03), defining the scope of accredited activity, and in the case of flexible scope, its control (S14 with annexes), or making reference to accreditation (S05).

During the assessment, members of the assessor team shall keep records of the work done, which shall clearly show the scope and object of the assessment performed, as well as any general and special findings. They shall normally use the prescribed forms for making records. Each assessor shall normally enter into the corresponding checklist records of the assessment carried out before and during the assessment visit; into the "Report of witnessed audit/verification" records of witnessing the certification or verification procedure; and into the form "Report of actions" records of assessment carried out after the assessment visit. In the case that some other format of record is used instead of the form, they shall make sure that it contains equivalent information and that it is adequately transparent. Observations, especially nonconformities, shall be formulated by the assessors clearly, unambiguously and factually, and they shall make sure that the actions suggested by the auditee are described in the same way, and that the proposed actions and time limits for their implementation correspond to the extent of the nonconformities found and the related risks (see 5.2.5).

The assessors shall examine the scope of accreditation to check that it is presented clearly and unambiguously, and that it is in compliance with SA's rules (S14 with annexes). Finding an essential difference between the description of the scope and the actual performance of activity by the accredited CAB shall mean nonconformity. Other minor corrections or indications in the scope shall be noted by the assessors during the assessment into the applicable Annex or into the scope for initial assessment or extension and attached to the assessment report.

When an expert is included in the assessor team, he/she shall perform the work in cooperation with one of the assessors, who shall decide on the appropriate way of cooperation with regard to the expert's previous experience and the circumstances of each assessment. The assessor may make preliminary arrangements with the expert as to his/her tasks and manner of performance, or they may perform the assessment together. The assessor shall review all the reports prepared by the expert.

Should there appear, during the assessment, any doubts as to the possibility of continuing the assessment procedure, or about dealing with individual findings of the assessor team, or any other dilemmas (e.g., unexpected situations affecting the course of assessment, the auditee not being prepared or disagreeing with the team's methods of work or findings), that cannot be resolved by the team alone, the lead assessor shall contact the coordinator to that effect. The coordinator shall forward the information to the relevant person(s) within SA, when necessary, and see to it that the lead assessor receives appropriate guidance as soon as possible. The assessor may directly contact the relevant person (e.g., the accreditation sector manager).

4.1 Assessment techniques

Examining documents shall include examination of the system documentation, records, organisation charts, plans, reports and other documented information in physical and/or electronic form and takes

place before and/or during the assessment. In doing so, the evaluation committee shall assess the adequacy of the documented information, as well as its management; e.g., issuance (preparation and authorization) of documents, distribution or accessibility of documents and protection of the integrity of the content and control of changes.

Accessing to documents shall mean examining various documented information (e.g., personal folders, reports and other technical records as well as quality records) which it may not be convenient or possible to be provided to SA before the assessment. By examining these documents, the assessor shall obtain information on the auditee's control of procedures, respect of the given rules and procedures, and on the efficiency of regulatory framework.

Interviewing the representatives of auditee shall help the assessor to obtain additional explanations and information, to assess professional competence and knowledge or the respect of the regulatory framework.

Examining the resources shall include examination of the availability, suitability and control of the resources (e.g., facilities, equipment, materials, and personnel).

Witnessing the performance of activities within the scope of accreditation shall normally be performed at each assessment on a chosen part of the activity and at chosen sites. Whenever possible, it should involve the monitoring of the regular activity of the auditee. Otherwise, the defined activities may be performed for the purpose of assessment only (as a demonstration); however, it should be agreed in advance with the auditee that he shall treat such a case in the same way as regular work for customers, and follow all the defined rules and procedures.

Verifying to ensure the validity of results of conformity assessment based on the validations/verifications made and on the mechanisms for controlling the validity of results.

In assessment, the assessors shall use:

- **horizontal assessment method:** checking individual element of the management system from several points of view and in different fields of implementation, and
- **vertical assessment method:** checking the performance of the management system in carrying out the basic process of the accredited activity (e.g., examination of all records, resources used, rules followed and the like, in carrying out an order).

4.2 Scope of assessment

Individual activities or elements of the management system shall be sample checked by the assessors. By doing so, they shall make sure that the chosen sample comprises a sufficient and representative part of all the activities and resources (also taking into account the type and planned scope of assessment and the assessor's role in the assessment).

When selecting the sample, the scope and the method, the assessors shall consider the risks related to individual processes/sub processes.

At the initial assessment, the assessor team shall assess the compliance and efficiency of all elements of the management system, determine the fulfilment of all the requirements for accreditation, and assess whether the auditee will be capable of meeting them after obtaining accreditation. Re-assessments shall involve – the same as initial assessments – horizontal examination of all elements of the management system.

At each surveillance visit, **horizontal examination** of some elements (about one third of all requirements for accreditation) shall be made, so that all the elements are assessed through

surveillance at least once in an accreditation cycle. Horizontal examination should constitute an integral examination of individual system element. The assessors shall determine whether an element of the system is adequately covered, whether adequate procedures are defined in its relation, whether they are respected and efficient (adequately supporting the activity of the accredited CAB). For this purpose, the assessors shall review the system provisions in the respective field, check through conversation with the staff their knowledge and understanding, and determine the fulfilment of the defined provisions and their efficiency by examining a representative sample of records related to the implementation. The conformity of other elements with the requirements of the standard shall be checked through vertical assessments. **At least one vertical assessment** shall be carried out at each assessment visit. In selecting an example for vertical assessment, an even representation of different accreditation activities shall be considered in addition to the requirement that vertical assessment shall be complemented by other methods of assessment (e.g., witnessing). Detailed provisions regarding these aspects for individual fields are defined in annexes hereto. Each assessor shall note separately into his/her checklist the elements that have been assessed in an integral way (elements of requirements, and – with technical assessors – also elements of the accredited activities), and the vertical assessments performed. The lead assessor shall also prepare and add to his/her report a survey of the elements of the requirements assessed in an integral way for the current accreditation cycle, taking into account the work of the complete assessor team, and suggest elements to be assessed in next assessment.

In addition, during each regular surveillance, at least:

- the effectiveness of the actions implemented by the client in order to eliminate the nonconformities found at previous assessment shall be checked. In doing so, the assessors shall use the records of the accredited CAB referring to the consideration of individual findings (cause analysis and extent, any additional actions defined, checking implementation and effectiveness of actions);
- the effect and control of possible changes in the accredited CAB shall be assessed and reported in compliance with the requirements of S03;
- the performance of the management system (with review of records of internal audits, management reviews, nonconforming work, corrective actions, improvements and complaints, appeals, risk control ...), and that the system includes all the main and supporting processes and sites at which accredited activities are being performed, shall be checked;
- the performance of procedures (e.g., witnessing the performance, records of activities to ensure the validity of results) shall be checked;
- communications with customers regarding orders and contracts shall be reviewed, as well as reporting, including reference to accreditation (paying particular attention to assessment of conformity of the contents of reports/certificates with the scope of the accredited activity);
- the compliance of resources and their maintenance (e.g., training/education of personnel, equipment maintenance/calibration, state of the facilities and maintenance of environmental conditions, materials used, and services) shall be checked;
- the relationships (status and operational) between the accredited CAB and the site at which the activity from the scope of accreditation is being performed shall be checked, when another legal entity is registered at the site;
- data on cross-border activities or changes to those activities shall be checked;



- the maintenance of independence and assurance of impartiality of operation of the accredited CAB (particularly important in certification bodies and type A inspection bodies) shall be checked;
- reference to accreditation shall be checked for compliance (S05) with particular attention, when the activity from the scope of accreditation is performed at a site where another legal entity is registered;
- compliance of indications in Annex to Accreditation Certificate shall be checked against the rules for presenting the scope and for compliance of actual performance of the accredited activities with the defined scope;
- the scope of other types of conformity assessment shall be checked, which are performed in support of the activity from the scope of accreditation, but are not specially accredited (e.g., internal calibrations, testing performed within the scope of inspection or certification);
- the compliance of maintaining flexible scope and control of changes in accordance with S14 and annexes thereto shall be checked, when relevant.

When the scope of accreditation is flexible in part or in whole, assessment of the process of introducing changes into the scope shall be carried out, normally by examining one or more (or all, when necessary) representative cases, to be selected by taking into account the related risks. In the case of flexible scope, particular attention shall also be paid to the validation/verification processes, to ensuring metrological traceability and validity of the results, and to the control of changes in the relevant normative documents. Prior to assessment, the assessors shall get familiar with the current state of data about the scope on the list maintained by the accredited CAB.

Also, a representative sample of all the activities shall be assessed with regard to the scope of accreditation within one accreditation cycle. Detailed provisions on these aspects are defined for individual sectors in annexes hereto. Other types of conformity assessment activities, which are performed in support of the activity from the scope of accreditation, but are not specially accredited, shall also be addressed separately, when necessary. When additional members are included in the assessor team to assess those activities, cooperation between them and the technical assessors assessing the activities from the scope of accreditation is important.

When the accredited activity (or individual key activities) is performed at different sites, the sites at which the assessment will take place shall also be selected when planning the assessment. Normally, all the sites shall be included in initial assessments; later on, an appropriate sample shall be chosen from among the sites for each assessment, so that within one accreditation cycle, the complete range is assessed. The choice of site shall be made by SA during assessment planning, while the assessors may suggest changes at any assessment stage, when they consider it necessary. When the accredited activity is performed at cross-border sites, the procedure shall be carried out following the rules laid down in D05-03.

The scope of the assessment carried out shall be evident from the records of the assessor team, and should follow the planned scope of assessment, except when circumstances dictate changes. Any deviations necessary in order to adapt to new findings or to other circumstances shall be explained by the assessors in the checklist, and shall be taken into consideration when giving recommendations for next assessment, while the lead assessor shall record any substantial deviations in the assessment report.

The assessor team shall always make sure that the deviations do not affect the integrity of assessment, so that it is carried out to the extent needed to determine the fulfilment of accreditation requirements. Any major deviations from the assessment programme shall be coordinated by the members of assessor team with the lead assessor and the auditee. Should there be any significant obstacles to the implementation of the planned assessment, the assessor team shall propose additional assessment, when necessary.

5 DESCRIPTION OF THE PROCEDURE

5.1 Pre-assessment activities

5.1.1 Preparation for assessment visit

Members of the assessor team shall receive from the coordinator information about a planned assessment, and about the scope of accredited activities to the assessment of which they have been assigned. The assessor intended to cooperate with an expert shall also be informed to that effect. When the assessors find themselves competent for carrying out the planned assessment activities, and that there exist no circumstances which would affect their independence and impartiality, they shall confirm their participation. They shall inform the coordinator of any links or relationships with the CAB under assessment, even if they consider that these do not affect their impartiality.

The range of documentation needed for the preparation shall depend on the role of the member of the team, the type of accredited activity, and other, specific circumstances. Each member of the assessor team shall normally receive a part of the auditee's system documentation (at least a list of applicable documentation, and the lead assessor additionally at least the quality manual or general management system documentation), reports of previous related assessments (which had not been conducted by the assessor in person), as well as other information and guidance (about changes, elements defined to be assessed their respective special data on the auditee's activities, any special directions for performance of the assessment ...). The assessor who will cooperate with an expert shall normally also receive the documentation and information intended for the expert.

Normally, assessors shall ensure themselves access to technical standards, regulations, guides and other publicly accessible documents, which they need for assessment. SA will only ensure these documents in special cases, upon previous arrangement. Each member of the assessor team shall examine all the documentation needed for preparation and implementation of his/her part of assessment in due time. Should the assessor find that he/she needs other documents or data besides those received, he/she shall arrange this with the coordinator. Also, he/she shall forthwith inform the coordinator upon finding any essential deficiencies or circumstances which could significantly affect or even jeopardize the implementation of assessment.

When a foreign assessor or expert, who does not understand Slovene, does not receive documents which are crucial for proper preparation for the assessment in a format enabling the use of machine translation, or when this does not ensure an understandable translation, and therefore they need the documents translated into English, they shall ask the coordinator to provide the documents in a different format or to provide translations.

The assessors shall schedule the course of their respective parts of assessment by following the plan of elements to be assessed – if it has been made – and the general instructions on the necessary scope of assessment under 4.2 below and annexes hereto; data on the scope of implementation of previous

assessments of the same auditee; as well as findings and recommendations by previous assessors, and the findings of examination of the auditee's documents. They shall choose a detailed assessment model taking into account the risks, based on the nature of the accredited activity and all the information on the accredited CAB. When the assessor considers that the plan needs changing, he/she shall notify the coordinator to that effect.

Each assessor shall serve to the coordinator a list of procedures/activities of the accredited CAB which he/she intends to witness, as well as other details which affect the organisation and course of assessment (e.g., witnessing field work, need for collaboration with other members of the assessor team). The lead assessor shall make a draft assessment programme (scope of assessment for horizontal assessment, witnessing, work schedule; team meetings; and meetings with the auditee). In collaboration with the coordinator, he/she shall ensure that the programme is aligned with other members of the assessor team.

The lead assessor shall ensure that the members of the assessor team, before the assessment visit (e.g. through video conference, or by e-mail), or before the introductory meeting on the day of the assessment visit, agree on the course of assessment and distribute the work among themselves.

5.2 Assessing at auditee's site

5.2.1 Introductory meeting

The introductory meeting shall be prepared and conducted by the lead assessor. All members of the assessor team, and the representatives of the auditee responsible for the activities from the accredited scope, shall attend the meeting.

The purpose of the meeting shall be to present the assessment participants and the assessment system, and to reach an agreement on the course of the assessment. The introductory meeting shall typically include:

- presentation of the assessor team and other participants;
- presentation of the purpose of assessment (initial assessment, surveillance, re-assessment);
- presentation of the principles governing the assessment procedures (impartiality, confidentiality, professionalism, independence, sampling principle, possibility to assess other points which are not on the programme);
- explanation of the assessment procedure (in particular: finding and reporting of nonconformities and defining corrective actions);
- accreditation scope under assessment (Contract, scope of initial assessment, Annex to Accreditation Certificate);
- presentation of the planned course (programme) of assessment (approval, changes, suggestions);
- micro-planning of the visit (persons, facilities, time, breaks, team meetings, interim and closing meeting);
- questions and suggestions of the auditee.

The course and scope of the meeting shall be adapted to the specific situation at the auditee's site as well as to the extent of previous experience of the auditee in accreditation and assessment process.

When an unannounced extraordinary assessment based on information obtained on the performance of the accredited CAB is carried out by visiting the site, the assessor shall serve an announcement of assessment to the client prior to starting the assessment.

5.2.2 Assessment

Assessment shall be the basic activity of the assessor team. The general rules and methods of work are defined in the previous chapter, while the specifics for individual fields of accreditation are described in annexes hereto.

Assessment shall be carried out for the scope of activities as specified in the Annex to the Accreditation Certificate and/or the Contract on establishing and maintaining accreditation, or its annexes. The assessor team, when competent, may accept minor changes of this scope in the course of visit, provided that this would not substantially affect the performance of the assessment (sufficient time available). In any case, this shall be subject to agreement with the lead assessor, who shall make a note to that effect in the assessment report (OB05-14). When the auditee expresses his decision to reduce the scope of accreditation during the visit, the assessor team must obtain a written statement to that effect from the auditee's legal representative, which they shall attach to the assessment report, and make the necessary adjustments to further course of assessment. When the auditee's decision to reduce the scope of accreditation is the result of nonconformity/ies found, such statement may be given as suggested action.

Each member of the assessor team shall complete a checklist showing his/her scope and method of assessment with reference to the elements of the management system checked (e.g. referring to individual clauses of the standard), with reference to organisational units or fields of activity of the CAB under assessment, and with reference to the scope of accreditation (checked, witnessed procedures, methods,...). The assessors shall also make notes into the checklist of findings which are not considered to be nonconformities, but which give a complete picture of the fulfilment of accreditation requirements, the condition of the accredited CAB and its activities, and which will help in making accreditation decisions and in planning next assessments.

When the client performs testing or calibration – within the scope of his activities that are subject to assessment – the form OB05-18 (ILC/PT or the review of other forms of ensuring the validity of results) shall constitute a part of technical assessor's report. Technical assessors shall note in the checklist their conclusions as to the adequateness of the instruments used for assuring the validity of the results of testing or calibration.

Any nonconformities found shall be separately entered by the assessors into the form "Report of nonconformity" (OB05-15). A record of nonconformity shall include the observation and the respective clause of the standard providing the requirements for competence, or reference to some other requirement for accreditation (from S03, S05 or S14 and annexes, from the scheme).

If a representative of the auditee with the necessary authorisations is present, it is advisable that the assessors agree with him/her on a suggested action during the very course of the assessment.

Should the auditee contest the nonconformity or disagree with the proposed actions, the assessor shall first consult the lead assessor or other members of the assessor team. When necessary, the assessor team may also consult SA.

Should the assessor team and the auditee – despite consultation and additional explanations – not be able to reach consensus about a nonconformity found or the necessary action, a note to that effect shall

be made in the Report of nonconformity (OB05-15), and the lead assessor shall inform the client of the procedure of filing an appeal against the nonconformity. When the disagreement of the client would impede the continuation of the assessment, the assessment shall be terminated (see 5.2.6 below); when not, the team shall proceed with their work.

5.2.3 Interim meetings of assessor team

The purpose of interim meetings shall be to co-ordinate the work of the assessor team, to plan further course of assessment visit, and to get ready for meetings with the auditee's representatives. They shall be held, when necessary, but at least once a day. The lead assessor shall take care of organization and of implementation of the meeting.

During the assessor team meeting preceding the closing meeting, the lead assessor in cooperation with the other team members shall draw up a report of the assessment (OB05-14). In the report he/she shall state:

- the scope of accreditation assessed (with unambiguous reference to an annex to the contract, or to Annexes to Accreditation Certificate and any possible changes agreed upon – description and/or reference to corrections in enclosed documents);
- the names and addresses of the sites assessed (if more than one);
- the designations of all nonconformity reports;
- a summary of the scope and course of the assessment and any derogations from the assessment programme;
- a summary of positive and negative findings of the assessor team (which may include a description of identified risks and opportunities – any proposals for improvement should be given, including a description of the objective of the improvement, but not concrete solutions) in relation with:
 - the organization
 - the suitability and stability of the management system;
 - the competencies and authorities of the key personnel;
 - the suitability of internal organisation, and of procedures, facilities, equipment and other resources; whether they inspire trust in the quality of the assessed body's services, taking into consideration the quantity and nature of the work it performs;
 - the implementation and efficiency of the actions to eliminate the nonconformities found at previous assessments;
- any specifics of the assessment (changes, issues ...) and arrangements with the auditee.

A technical assessor carrying out an assessment alone (e.g. extraordinary assessments, additional assessment to review actions) shall prepare the report him/herself. The report shall include only the information related to the particular assessment.

5.2.4 Meetings with the auditee's representatives

Meetings with the auditee's representatives shall normally be held at the beginning and at the end of each assessment day. At the meetings held at the beginning of the assessment day, the course of assessment shall be agreed as described under 5.2.1 herein or adapted accordingly to specific situation. At the meetings held at the end of each assessment day, the members of the assessor team shall briefly report of the assessment carried out and of their key findings. They shall present and confirm the nonconformities found in the course of the assessment.

5.2.5 Closing meeting

The closing meeting shall be held at the end of the assessment and shall normally be attended by the complete assessor team, and the representatives of the auditee responsible for the management system and for technical management (responsible representatives of all the activities). The presence of the auditee's senior executive management is also recommendable. When appropriate, the assessor team may arrange for a separate meeting with the top management. The closing meeting shall normally be conducted by the lead assessor.

The meeting may be carried out in several parts, as required by the course of assessment (e.g., when individual assessor is only present during a part of the assessment visit).

Normally, the closing meeting shall include:

- expression of gratitude for hospitality and co-operation;
- presentation of the participants (as appropriate);
- explanation of the purpose and the agenda;
- summary of the assessor team's methods of work and the work done;
- summary of general findings (also the positive ones and possible improvements, but without concrete solutions);
- presentation of the nonconformities found;
- confirmation (or rejection) in writing of individual nonconformities by the responsible representatives of the auditee;
- specification of the proposals and deadlines of actions for individual nonconformities found;
- reservation – explanation as to the sampling principle in assessment;
- prompted explanation as to the confidentiality of data and information;
- explanation as to the continuation of the accreditation procedure (reporting on the actions, review, decision on accreditation);
- copying of the assessment report with annexes and presenting a copy to the auditee;
- client's questions;
- conclusion.

The course, scope and detailed contents of the meeting shall be adapted to the specific situation at the auditee's site, as well as to the extent of auditee's previous experience in assessment and accreditation process.

The purpose of the meeting shall also be the definition and approval of proposals of the actions and deadlines for the elimination of the nonconformities found, except when they have already been coordinated during the course of assessment. The auditee shall give the proposals of actions and the deadlines. The assessor team shall make sure that the nonconformities are made clear to the auditee, that the proposals of actions and deadlines are appropriate with regard to the known risks related the nonconformity, and that they are defined in an unambiguous way. This means that, in the case of finding significant nonconformities in an accredited CAB, with possible direct impact on the performance or the results of the accredited activity, accordingly short deadlines should be agreed for the implementation of actions, or the proposal of action shall include a statement by the auditee not to perform the accredited activity affected by the nonconformity until the implementation of the action has been confirmed. Any discussions on the choice of actions shall be communicated by the assessor team in such a way as to make it clear that the responsibility for the choice is on the side of the auditee.

In the case of **critical nonconformities and lack of trust** in the capabilities of the accredited CAB to tackle them, the assessor team shall propose **immediate suspension of accreditation**.

When deciding on deadlines, it shall also be taken into account that the **maximum deadline for reporting of actions** by the accredited CAB shall be **2 months (or 6 months in the case of initial assessment)**. All the actions, in relation to which the assessors shall examine evidence of implementation in order to be able to give their recommendation, shall therefore be implemented before this deadline.

The assessor team will decide, on the basis of the nonconformities found and the defined actions, as to which actions can be reviewed by documentation, and which actions will require reviewing through an additional assessment visit.

At the end of the closing meeting, the team shall serve to the auditee's representative a copy of the assessment report with annexes (nonconformity reports, scope of accreditation together with corrections, if any).

When the report cannot be concluded at the assessment, e.g., due to the large extent of assessment, or due to difficulties in communication within the assessor team (long lasting assessment divided into several parts, at multiple locations), the lead assessor shall subsequently retrieve data from all members of the assessor team and prepare the report immediately after the conclusion of the assessment at the auditee, normally within a couple of days. In such cases, the lead assessor shall, when drawing up the report, pay particular attention to any information differing from that given orally at closing meeting/s, which must be specially clarified in the report. The lead assessor shall then send the report to the coordinator, or directly to the auditee, and as information to the coordinator.

When the proposals of actions cannot be defined, or it would not be reasonable to define them at the closing meeting (when a more detailed analysis of the cause is necessary, or when the action has to be approved by a person who is absent), the assessor team may agree that the auditee will **subsequently prepare proposals of actions** and deadlines for their implementation. As this option brings about more complex further treatment and more possibilities of misunderstanding, the assessor team should only use it when it is justified, and only for individual actions. In such cases the assessor team shall make sure in particular that the auditee fully understands the nonconformities found.

Thus, only the observation shall be confirmed by signatures on the nonconformity report, and the deadline (typically shorter than one week) by which the proposal of action together with the cause analysis shall be communicated to SA, shall be entered instead of the action. The lead assessor shall note this agreement into the assessment report and draw the coordinator's attention to it.

The coordinator shall forward the subsequently sent proposals of actions (on the form OB05-07) to the assessor team. Each member of the team shall examine the proposals (for adequacy of proposed action with respect to the cause analysis and extent of nonconformity, the adequacy of proposed attached evidence and the deadlines) referring to his/her findings, and approve or reject them, with an explanation. When judging the adequacy of the proposed deadlines they shall take into consideration that the deadline for reporting on the implementation of action will be 2 months from the conclusion of the assessment visit, and not from the date of examining the proposals. They should also define whether the actions can be reviewed by examining the documentation, or whether any of the actions would need reviewing through an assessment visit. In the case of proposals of actions for the findings

of an expert, both the expert and the assessor cooperating with the expert shall state their opinions. All the proposals shall eventually be reviewed by the lead assessor, who shall also state his/her opinion.

5.2.6 Termination of assessment

Should the assessor team while performing assessment at the client's site find out that the conditions for the performance of assessment have not been met, or that there are such deficiencies in the management system and in the performance of the activities that the assessment could not be carried out according to the programme, the lead assessor shall organize an internal meeting of the assessor team members. At the meeting, the team shall verify and align their positions as to whether the assessment needs to be terminated, write down the nonconformities found so far, and terminate the assessment. The lead assessor shall draw up an assessment report (OB05-14), indicating all general findings and circumstances that have entailed termination of the assessment. The team shall hold a meeting with the client, at which they shall present their decision on termination of the assessment visit, the circumstances that have entailed the termination, and explain the rules for filing an appeal. Circumstances permitting, the client shall propose actions for the recorded nonconformities, otherwise, the actions will be defined subsequently. The team shall, as soon as possible (within two working days at the latest) after the visit, prepare and communicate to SA a recommendation for decision on accreditation (OB05-17), in which they shall explain the circumstances for termination of assessment and propose further steps, i.e., suspending or withdrawing accreditation, or in the case of initial assessment, refusing to grant accreditation and terminating the accreditation procedure, or repeating the assessment, or carrying out an additional assessment.

The team shall propose the repetition of assessment of an accredited CAB when they estimate that the circumstances impeding the performance of the assessment could be eliminated in due time, so that it will be possible to carry out the assessment in accordance with the rules, and that, in the case of an already accredited CAB, the findings of the assessment do not indicate to any essential deficiencies in controlling the accredited activity.

5.2.7 Additional assessment

When the necessary scope of assessment could not be carried out in the planned time or on the planned date, the assessor team shall recommend an additional assessment to be performed.

Additional assessment can be recommended after the assessment on the planned date has been carried out (e.g., due to unexpected circumstances, critical issues that have revealed themselves during the assessment, or barriers to its implementation), or after the review of the report of actions. When it is subsequently established that actions to eliminate important nonconformities cannot be reviewed through documentation only, additional assessment shall be recommended to review the actions. When a wider problem is detected in the report of actions that impedes the recommendation for maintenance or grant of accreditation, additional assessment shall be recommended.

An explanation of the circumstances and reasons dictating additional assessment, as well as the expected scope of the additional assessment needed shall be given with the recommendation.

5.3 Post-assessment activities

The lead assessor shall immediately (normally on the following working day) after the assessment visit inform the coordinator on the course of the visit. He/she shall draw particular attention to any differences between the planned and implemented scope of assessment, which shall also be noted in the

assessment report (OB05-14). He/she shall also draw attention to any other special events or arrangements which may affect further course of the procedure or SA's collaboration with this auditee (arrangement on subsequent sending of proposals for actions, review of corrective action with additional visit, and the like).

All members of the assessor team shall send, within 7 days of the assessment at the latest, to the coordinator their checklists with any necessary annexes (e.g., OB05-18), the expert/assessor opinion (OB05-63) and documents needed to calculate the cost of assessment, while the lead assessor shall also send the master copy of the assessment report with annexes. When a part of the assessment is carried out by a technical assessor independently, he/she shall provide to the coordinator originals of all the reports from that part of the assessment (e.g., report of actions, and, in the case of assessment to review the actions, report of the assessment; report of witnessed audit/verification; report of nonconformities). When the assessment is carried out in multiple parts, the lead assessor shall prepare, normally within 1 week of after the conclusion of the assessment, a supplemented report of the assessment, and forward it to the coordinator, who shall then serve it to the client.

In the expert's/assessor's opinion (OB05-63), each member of the assessor team shall make a brief summary of their findings in the assessment carried out, and give their opinion as to the fulfilment of the accreditation requirements in their particular fields of assessment, regarding:

- the adequacy of internal organisation and procedures (whether they ensure proper control of the accredited activity and maintenance of trust in competence);
- fulfilment of the key requirements with regard to the nature of the accredited activity (the set of key contents differs between fields of accreditation; it also depends on the role/assignments of the assessor/expert in the assessment, and includes, e.g. impartiality, legal status and organizational structure, personnel competencies, provision of measurement traceability, validation/verification of methods/procedures, participation in ILCs, and other mechanisms for ensuring the validity of results).

5.3.1 Assessing the actions

In reviewing the report of actions, the assessor team shall confine themselves to assessing the adequateness of the action with regard to the defined nonconformity, taking into account the proposal of action given at the assessment, the findings of the cause analysis and the extent of nonconformities (e.g., whether they indicate the need for additional or different actions), and any explanations of derogation from the proposed action. Should the team, while reviewing, randomly find any (possible) new nonconformities, they shall, all by taking into account the related risks, decide on checking them at next assessment, or, when it is not possible to give recommendations for maintenance or grant of accreditation without clearing the issue, propose an additional assessment (see item 5.2.7).

5.3.1.1 Assessing the adequateness of actions by examining the documentation

Each member of the assessor team shall receive from the coordinator a report of actions (OB05-16) together with the documentation in support of the statements made in the report, and in the case of changes of scope of accreditation, also a draft Annex to Accreditation Certificate. The assessor cooperating with an expert shall also receive the complete documentation intended for the expert.

Each member of the assessor team shall review the implementation of the actions related to the nonconformities found by them.

In the report (OB05-16), the assessor shall explain the findings of the review for each nonconformity separately, and confirm the adequateness of the action, or request supplementation of the report, as appropriate. When the assessor considers that the auditee needs to be informed of the contents and conclusions of the review, he/she shall order the coordinator to provide the report to the auditee, even when no supplements of the report are needed. The assessor cooperating with an expert shall also receive for review the expert's report of reviewing the actions against the nonconformities which they have defined together.

Normally, the assessor shall make a request to supplement a report of actions when:

- the implementation of an action is not evident or understandable;
- the implemented actions and/or the attached evidence do not match the proposal given at the assessment, and the reason for that has not been explained in the report;
- the implemented actions are obviously inappropriate and/or deficient, and when it is evident that the nonconformity has not been properly addressed;
- also possibly, the findings of cause analysis and the extent of nonconformity have not been clearly defined, or they are obviously inappropriate (e.g., the nonconformity found has merely been repeated).

Normally, the reports may only be supplemented once. Should it not be possible, even after the supplementation, to determine that adequate actions have been introduced, the assessor team may propose refusal or withdrawal of accreditation (in the whole scope or part thereof). In such a case the assessors shall draw up recommendations for the decision chosen, including a detailed explanation. Regardless of that, the communication on the actions shall continue, when it is a matter of misunderstanding or deficient exchange of information (especially in addressing more complex issues).

In the draft annex to accreditation certificate, every technical assessor shall check the adequateness of data and statements for all the activities from the scope ascribed to them (not just those they assessed in more detail at the assessment concerned). The lead assessor shall, after the review by the rest of the assessor team members, check whether all the findings and arrangements from the assessment, as well as any subsequent corrections or comments by the assessors, have been properly considered, and whether the way of stating conforms to the rules.

5.3.1.2 Assessing the adequateness of actions through an additional assessment visit

Having received the report of actions, the team shall examine it, and then pay an additional visit to assess the adequateness of the implemented actions necessitating the additional visit, not giving any additional nonconformities. The procedure itself shall run as described above. Records of the review and its findings shall be made in OB05-16, and at the conclusion of the additional visit, an assessment report shall be drawn up (OB05-14), the contents of which shall be adequately adapted to the scope and purpose of the assessment carried out. Supplements to the evidence of implementation of actions may be made only once after the conclusion of assessment.

5.4 Recommendations for decision on accreditation

After the conclusion of assessment, each technical assessor shall draw up and sign a recommendation for decision (OB05-17) for their respective fields of assessment and serve it to the coordinator. The recommendation should clearly indicate to which part of the scope of accreditation it refers (through unambiguous reference to the corresponding document – e.g., Annex to Accreditation Certificate). The

recommendation and its annexes shall clearly indicate to all the details of presenting the scope (e.g., changes, corrections with regard to the valid revision of Annex).

The assessor cooperating with an expert shall also review the expert's recommendation (the same as all parts of the expert's report before). The assessor shall only make his/her recommendation after having reviewed and, if necessary, provided for harmonisation of the contents of all the expert's reports and recommendations.

The lead assessor shall receive from the coordinator all the reports of the other assessor team members, or allow them access to the information system, including the reports and recommendations of the assessors who have carried out part of the assessment outsourced to a foreign accreditation body, and shall draw up his/her recommendation based on his/her own conclusions and on the recommendations from other team members.

The lead assessor's recommendation shall refer to the complete scope of activities being the object of accreditation procedure.

The assessors may deliver recommendations for different decisions referring to individual accredited activities (parts of accreditation scope).

Type of decision	Reasons/circumstances dictating the recommendation of individual types of decision
First grant of accreditation	Initial assessment has shown that the auditee meets all the requirements for accreditation for all the activities from the scope of accreditation, i.e., that the nonconformities, if any, have been properly eliminated.
Maintenance	When no nonconformities have been found by surveillance, or when the nonconformities found have been eliminated through proper actions (the assessors may deliver a positive recommendation even when actions related to individual nonconformities, which do not have an essential or short-term effect on the accredited activity, have not yet been fully implemented, or when their efficiency has not been fully verified).
Extension of scope	Assessment for extended scope has shown that the auditee meets all the requirements for accreditation for additional activities to extend the scope of accreditation.
Withdrawal of part of the scope (reduction)	In the case of reasons for withdrawal, as stated in S03, clause 6, when they refer to a part of the scope of accreditation.
Refusal to extend accreditation*	<ul style="list-style-type: none"> - During assessment of extension, the client has not allowed the assessor team to obtain the required evidence and/or clarifications on fulfilment of accreditation requirements (the client is not prepared for assessment, or he does not provide to SA access to all the information). - The client has not eliminated the nonconformities by implemented actions, related to the extension.
Suspension*	In the case of reasons for suspension from S03, clause 6.

Reinstatement of accreditation after suspension	During suspension, an extraordinary assessment following the implementation of the actions finds the accreditation requirements to be fulfilled.
Withdrawal of accreditation	In the case of reasons for withdrawal, as stated in S03, clause 6, when they relate to the complete scope of accreditation.
Refusal to grant accreditation and termination of procedure*	<p>- For reasons on the side of the client, it is not possible to obtain, within the framework of the assessment activities already carried out or planned, all the evidence and/or clarifications on fulfilment of accreditation requirements (the client is not prepared for assessment, or he does not provide to SA access to all the information), and they cannot be obtained in reasonable time.</p> <p>- The client has not eliminated the nonconformities by implemented actions.</p>
Termination of procedure	The conditions for carrying out the assessment have not been met (the client is not prepared for assessment, or he does not provide to SA access to all the information needed to establish fulfilment of the requirements).
Editorial correction of Annex / Accreditation Certificate	Editorial mistakes have been found in the issued Annex / Accreditation Certificate, or it is a matter of material errors, but it is obviously a writing error, therefore the corrected Annex / Certificate is valid as from the date of issue of the Annex / Certificate it replaces.
Carrying out additional assessment	<p>- Within the framework of the assessment activities already carried out or planned, the assessors are unable to acquire all the evidence on fulfilment of the requirements for accreditation (e.g., not sufficient time provided for assessment; significant specifics of the activity have been identified during the assessment that need to be addressed separately or additionally; obstacles to carrying out the assessment are present due to which the assessment could not have been carried out in the allocated time; while reviewing the implementation of actions, the assessor accidentally finds new important (possible) nonconformities, and therefore the recommendation for maintenance or grant of accreditation cannot be given unless the problem is clarified).</p> <p>- The adequateness of implemented actions cannot be assessed by examining the documentation (e.g., at the conclusion of the assessment it has been defined which nonconformity/ies will require review of evidence of implementation through additional assessment; the need for carrying out additional assessment has been established during post-assessment activities.</p>

* of the complete (applied for) scope of accreditation or part thereof

The assessment report and the recommendations of the assessor team members should show the general conclusion as to the stability of the accredited CAB's performance or its control of the accredited activities, which shall be taken into consideration when deciding on surveillance intervals and the scope of next surveillance.

In the recommendation for decision, the assessors shall also deliver special guidance and recommendations for the performance of next assessment. They shall define special guidance or strategies for the work of assessors as well as provide the information needed for planning and/or preparing the assessment programme. The lead assessor shall also deliver a survey of horizontally (integrally) assessed elements of requirements and define the elements he/she recommends to be the object of horizontal assessment in next surveillance.

In the recommendations, the assessors shall draw special attention to the particulars that need to be taken into account when planning next or future assessment/s (e.g., expected changes, cross-border work, other types of conformity assessment activities performed in support of the activity from the scope of accreditation).

Should the assessor team **while conducting the assessment find a situation requiring immediate action** by SA in accordance with the rules for suspension or withdrawal of accreditation (S03), the lead assessor shall draw up a recommendation for decision-making immediately after the finding (e.g., of nonconformity that affects the validity of the results of accredited activity), and serve it to the coordinator. When in the team's opinion, it is an urgent case in the public interest, where human life and health are endangered, they shall highlight this in their recommendation.

6 COMPOSED AND COMBINED ASSESSMENTS

An assessment visit for the same accreditation procedure shall sometimes be composed of several successive events. The lead assessor shall accordingly divide his/her work into individual visits, so that it is not duplicated, and at the same time, that the necessary scope of assessment is ensured. The assessment report shall in such cases be concluded after the complete assessment has been carried out, and the lead assessor shall provide to the coordinator updated information on the implementation of individual events. When the events are rather remote in time, a partial assessment report should be prepared upon conclusion of each event.

Assessments of several accredited bodies of the same client sharing the same management system shall be linked, whenever possible.

When the same lead assessor is appointed for all the assessments carried out in one or several events linked together, he/she shall plan the work in such a way as to ensure the appropriate scope of assessment carried out for all accredited bodies, without unnecessary repeating of activities (addressing in an inter-related manner the common elements of the system and the activities). When the management system and the activities of all the bodies are strongly inter-related (the same field of accreditation), the lead assessor may use only one form for reporting of all the accredited bodies; when not, he/she shall use a separate form for each of the bodies, but refer to the relevant other parts of the reports in the case of common elements and findings rather than duplicate the records of their assessment.

When individual assessments are separated in time, or when they are conducted by different lead assessors, these lead assessors shall be made familiar with the findings and recommendations of previous assessments of the same client, and shall take these into account when planning and carrying out the assessment.

7 EXTRAORDINARY ASSESSMENTS

Each assessor assigned to conduct an extraordinary assessment as a result of changes, complaints or other information on the performance of an accredited CAB, shall for that purpose receive from the coordinator documentation and information on the reason and objectives of the extraordinary assessment (form OB05-94).

Based on this, the assessor shall develop a plan and a reminder for the assessment and coordinate it with any other members of the assessor team. The assessor may request additional documents of the accredited CAB and/or additional explanations from SA, when necessary.

In the form, the assessor shall make reference to the parts of the reports showing the scope and the conclusions of the assessment related to individual objective, and deliver his/her opinion as to whether the findings of the assessment show that the assessment was justified or not.

When a complaint or some other information by a third person not wishing to be disclosed gave rise to extraordinary assessment, the assessor shall conduct the assessment in such a manner that the disclosure of the source of information is avoided to the greatest extent possible. The assessor shall therefore treat as confidential the information about the complainant or other source, unless this has explicitly agreed to the disclosure.

In assessing, issues shall be addressed systematically, when possible, by reviewing a larger sample of different cases, not just the one directly related to the given information.

8 CHANGES WITH REGARD TO PREVIOUS REVISION

In clause 3 and in item 5.2.5, warnings have been given on avoiding consultancy as to the choice of actions, and provisions on data confidentiality have been supplemented.

In clause 4, the obligation of the assessor to explicitly approve all reports of the expert, has been deleted; instead, a provision has been added in 5.4, that the assessor working with an expert shall provide for the review and alignment of these reports before delivering his/her recommendation.

Item 5.2.6, on termination of assessment, has been supplemented.

The instructions in 5.2.3, on preparing an assessment report for assessments carried out by a technical assessor alone, and the instructions in 5.2.5, on subsequent preparation of a report, have been supplemented.

The provisions in 5.3.1 have been changed so as to define more clearly the tasks of the assessor when reviewing the actions and changes in the annex to accreditation certificate.

Clause 5.4 specifies that the lead assessor shall have access to all the reports of other assessor team members, and not just to the checklists and recommendations. The decision on extension of validity of accreditation for GHG verifiers has been withdrawn.

There are minor corrections or supplements to the text also in some other parts of the text. All changes are marked.

9 TRANSITORY PROVISIONS

N/A



10 CONTROL OF THE DOCUMENT

A valid document shall be located in i4 (SA Information System). A clean copy shall be published on SA's website, and available in printed form at SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4.