

S03

# **RULES OF ACCREDITATION**

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#### **1 INTRODUCTION**

Accreditation is a technical, impartial, and independent procedure used by a national accreditation body to attest that an accredited CAB is competent to carry out specific conformity assessment tasks. Slovenian Accreditation (SA) performs accreditation procedures in all those fields in which there is a need or in which interest is expressed (see clauses 3 and 4).

SA operates pursuant to international standards and carries out its activities in a non-discriminatory way, i.e., by free approach to all those who satisfy the requirements for accreditation.

Accreditation procedure is always carried out on client's request. Decision for accreditation is voluntary.

The procedure for obtaining accreditation and its surveillance is defined in clause 5 (see also *Annex 1*) and shall be carried out in three main steps:

- 1. application for accreditation;
- assessment of the fulfilment of requirements for accreditation conducted by the assessor team (For the purpose of this document the term "assessor" shall refer to any person appointed by SA to an assessor team, regardless of their role in the team, i.e., as lead assessor, technical assessor or expert.);
- 3. decision on grant of accreditation.

Information on accredited CABs is publicly available in the Catalogue of Accredited CABs at SA's head office, and on SA's website.

#### 2 GENERAL PROVISIONS

This document lays down the procedure for accreditation of testing, medical and calibration laboratories, certification bodies, inspection bodies, verifiers on greenhouse gas emission reports, environmental verifiers and validation/verification bodies (hereinafter called "clients"), as well as the mutual rights and obligations between Slovenian Accreditation (hereinafter called "SA") and the client in procedure.

This document is one of SA's internal regulations, which lay down the requirements for accreditation and the rules of accreditation, of which SA shall maintain public record. Its provisions constitute a part of the Contracts on establishing and maintaining accreditation, which SA concludes with its clients. Valid copies of SA's internal regulations governing the requirements for accreditation and the rules of accreditation shall be available at SA's head office and published on SA's website.

#### 2.1 The rights deriving from accreditation and validity of accreditation

Through the grant of accreditation certificate, the accredited client shall obtain the right to use the accreditation mark when stating the activity for which he has been accredited and within the scope stated in the annex to the accreditation certificate.

Accreditation shall be valid until withdrawn, except for the GHG emission reports verifiers' accreditations, the validity of which is limited to maximum five years. SA shall undertake surveillance procedures to check the fulfilment of the requirements for accreditation by the accredited CABs throughout the validity period.



Normally, granted accreditation is not limited to the geographic areas in which the conformity assessment activity is performed. When conformity assessment is performed to *Regulation (EC)* No 1221/2009 (EMAS), or to *Regulation (EU)* 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, granted accreditation, if not specifically stated, shall mean carrying out conformity assessment within the European Union and the European Economic Community. Conformity assessment to the above-mentioned Regulations in third countries shall be specifically stated in the accreditation.

Termination of accreditation (i.e., suspension or withdrawal) shall not affect the validity of the reports/certificates/statements that the accredited CAB issued before the termination of accreditation, except in the case of conformity assessment schemes which include the performance of regular surveillance. The validity of those reports/certificates/statements shall expire on the date of first regular surveillance visit after the termination of accreditation at the latest.

The rules for the use of the accreditation mark and the rules for referring to accreditation are laid down in the document *S05*.

# 2.2 SA's obligations in accreditation procedure

SA shall carry out and conduct the accreditation procedure based on a "Contract on establishing and maintaining accreditation" (hereinafter called "the Contract"), which lays down the mutual rights and obligations between SA and the client in accreditation procedure.

In accreditation procedure, SA shall comply with Slovenian and international regulations relating to accreditation, as well as international accreditation rules.

SA shall carry out and perform all the activities and acts necessary to assess the client's competence for implementing tasks in the field of conformity assessment, and for maintaining the status of accredited CAB. Records to that effect shall be kept by SA for at least 12 years.

During the accreditation procedure, SA is bound to ensure confidentiality of the information it obtains about the client in relation with its assessment of the client's fulfilment of the conditions to obtain and maintain accreditation, except where otherwise stipulated by a legislative act in particular cases, or when the client gives his written consent to that effect. Any data obtained by SA during the accreditation procedure – except for the accreditation certificate and the scope of accreditation granted – are covered by professional secrecy in accordance with the Trade Secrets Act (RS OG No. 22/19) and shall be treated by SA as confidential in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, and standard SIST EN ISO/IEC 17011:2018 (Conformity assessment Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2017)), and may be used exclusively within the accreditation system, which shall apply throughout the term of validity of the Contract, and also after its termination. When there is a legal basis for disclosure of confidential data, or when SA has been authorised to do so through contractual agreement, and SA is therefore obliged to disclose confidential data, SA shall forthwith notify the client – unless it is prohibited by a legislative act – which confidential data they have disclosed and who they have shared it with. Exceptions on exchange of information between SA and other organisations are stated in sub-clause 2.2.1.



SA is bound to conclude the Contract with any client wishing to obtain accreditation, provided that the conditions laid down herein have been met.

After having examined an application, SA will refuse to start an accreditation procedure if it does not have in place an accreditation system for the technical field for which accreditation is sought.

SA may defer the start of an accreditation procedure when it does not have at its disposal the necessary assessors or other resources to carry out the accreditation procedure in reasonable time.

SA is bound to address any appeals by the clients according to the provisions hereof.

SA is bound to publish information on the conformity assessment activities for which it conducts accreditation, on the requirements for obtaining accreditation, as well as information on accreditation rules and the procedure.

When discontinuing a field of accreditation, SA is bound to lay down transitory provisions and to announce its intention to all interested parties. SA shall make public the news of the field discontinuation.

If, during the performance of the procedure for obtaining accreditation or during maintenance of accreditation, changes should occur to SA's internal regulations laying down the requirements for accreditation and the rules of accreditation, SA shall notify the client in writing or by e-mail of the changes and allow for a reasonable period of time, when necessary, for the client to adapt his operations to the changed requirements. Non-fulfilment of the changed requirements during this transitional period, however, shall not provide a reason for withdrawing the accreditation. Should the client, after the expiry of the transitional period, not adapt his operation to meet the changed requirements, this shall provide a reason for suspension of accreditation.

When the above-mentioned changes are such that they require modification of the Contract, SA will send to the client a new contract and set a suitable time limit for the client to sign the Contract. Should the client, even after a subsequent request by SA, not sign the Contract, this shall mean that the client has suggested withdrawal of accreditation.

SA is bound to maintain and enable public access to the data on granted accreditations and their status, including data on the scope of accredited activities of individual accredited CAB.

#### 2.2.1 SA's obligations in exchange of information with other organisations

SA shall:

- pursuant to the requirements of EA-2/13 M and Article 50(5) of Commission Implementing Regulation (EU) 2018/2067, exchange information with a foreign accreditation body under the conditions from sub-clause 2.3, indent 6 hereof;
- pursuant to IAF MD 23, in cases when:
  - SA makes a decision on granting or extending accreditation of a certification body for management systems for certification procedures in which the accredited body has included a foreign legal entity (e.g., representative, agency, franchise or sales office) which performs and/or conducts the management systems certification activities on its behalf and for its accreditation, and which is in a contractual relationship with the certification body for performing certification activities,



- SA receives an application for inclusion of a foreign legal entity into the scope of accreditation, or when
- SA is informed of inadequate work performance of such foreign legal entity,

SA shall communicate this information to the local accreditation body of the country in which this foreign legal entity operates;

- pursuant to Article 71(1) of Commission Implementing Regulation (EU) 2018/2067, by 31 December of each year, make available to the competent authority, i.e., the Ministry responsible for environmental issues, SA's accreditation work programme for the field of accreditation of verifiers on greenhouse gas emission reports containing the list of accredited verifiers, and in relation to each verifier the following information:

- the anticipated time and place of the verification of the accredited verifier, including the dates of anticipated witnessing of verifications, the address and contact data of the aircraft manager or operator where witnessing is to take place,
- information on whether SA has requested the national accreditation body of the Member State in which the SA-accredited verifier is carrying out verifications to carry out surveillance activities,

and where changes occur in the Work programme, inform the competent authority of the changes by 31 January of the current year;

- pursuant to Article 71(3) of Commission Implementing Regulation (EU) 2018/2067, by 1 June of each year, make available to the Ministry responsible for environmental issues and to the competent authorities of the Member States in which the verifier on greenhouse gas emission reports is carrying out verification activity, a management report for the previous one-year period, which shall contain details of newly accredited verifiers for verification of GHG emission reports, including the scope of accreditation, and in relation to each accredited verifier, at least the following information:
  - any changes to the scope of accreditation,
  - summarised results of surveillance/reassessment activities,
  - summarised results of extraordinary assessments, including the reasons,
  - any complaints filed against the accredited verifier and the actions taken by SA;
  - details of action taken by SA in response to the information shared by the Ministry responsible for environmental issues;
- pursuant to Article 43(5) of Commission Implementing Regulation (EU) 2018/848 and Article 33(2) of Regulation on organic production and processing of agricultural products and foodstuffs (RS OG No. 105/2022 (2608)), by 1 March of the current year, make available to the Ministry of Agriculture, Forestry and Food (MKGP) and the Administration for Food Safety, Veterinary Sector and Plant Protection (UVHVVR) a report on surveillance of the activities of organisations for inspection and certification in the previous year.

# 2.3 Client's obligations in accreditation procedure

By signing the Contract, the client undertakes, among other, to meet the requirements for accreditation deriving from the standards and documents, which lay down the accreditation rules, in particular:

- to permanently fulfil the requirements for accreditation in its full scope, and to provide evidence of their fulfilment;
- to adapt his work and organisation to the requirements for accreditation within the time limits set by SA;



- to ensure such level of co-operation with SA as to enable SA to assess the continuous fulfilment of accreditation requirements for all the sites at which conformity assessment activities are carried out;
- to ensure to SA access to his personnel, sites and equipment and to any information, documents and records needed by SA to assess the fulfilment of the accreditation requirements during the procedures of accreditation and surveillance or maintenance of accreditation;
- when performing, as a part or in support of the activities from the scope of accreditation, other types of conformity assessment activities for which he is not specially accredited, to define and maintain the scope of those activities with information which is equivalent to the definition of the scope of accreditation for this other type of conformity assessment activity, and to fulfil for them the relevant requirements for competence;
- when performing conformity assessment activities from the scope of accreditation abroad:
  - to allow the accreditation body of that particular country to carry out assessment for SA as subcontractor, provided that they meet the given conditions, or just to attend the assessment as observer;
  - to allow in such cases without informing in advance and obtaining consent, the local accreditation body and SA to mutually exchange all the necessary information, documents and records relevant to carrying out assessment at that client, as well as all other information, such as outcomes of assessments, complaints, market feedback etc., when the location abroad, which is included in the scope of SA accreditation, is also the holder of the accreditation of the local accreditation body;
  - to ensure full cooperation between the two accreditation bodies;
  - to keep SA informed about any changes in performing the conformity assessment activities from the scope of accreditation abroad and/or changes in the presence on foreign markets;
- to enable the witnessing of his performance of conformity assessment procedures, including witnessing of those procedures performed on his customers' premises, and in doing so, to ensure the assessors' safety in compliance with the regulations on safety and health at work;
- to enter, when relevant, into legally binding arrangements with his customers to ensure access and work to the SA assessor team when performing assessment of conformity assessment procedures at the site of the customers of this accredited body or SA's client in procedure for obtaining accreditation;
- to enable the training of assessor candidates and assessor monitoring (in connection with paragraph 4 of sub-clause 5.5);
- to use reference to accreditation exclusively in relation with conformity assessment procedures for which accreditation has been granted, and in doing so, to pay regard to all the provisions laid down in the document "Rules for the use of the SA logo, the use of accreditation mark and for making reference to accreditation (*S05*), including the restriction of using and making reference to accreditation way or in a manner which could compromise SA;
- to prevent other legal entities related to him from making reference to his accreditation;
- to take appropriate action in the case of perceiving unauthorised reference to his accreditation made by customers or other users of his services or by a third person;
- to take appropriate action in the case of perceiving data concealment or falsification, or any other fraudulent conduct in the field of the accredited activity;



- in the case of suspension or withdrawal of accreditation, to notify all the interested parties (clients, relevant state authorities ...) to that effect, and to immediately stop making reference to accreditation in compliance with the provisions of *S05* (this includes information published on the website, or the use of promotional material);
- to pay regularly, within the defined deadlines, his commitments deriving from accreditation procedures, as defined by the Rules on price formation for the services provided by SA (*S10*);
- to take part in investigation and handling of any complaints received by SA arising from his work and related to the accredited activities;
- to forthwith notify SA when he is held liable for committing an offence related to the scope of accredited activities;
- to currently inform SA of any important changes related to his legal or economic status, ownership or organisation, management or personnel, main operational policy, main resources, facilities, equipment, work procedures within the accredited activity, performance of conformity assessment activities abroad, or any other elements that might affect the accredited activity; and to:
  - notify SA in advance of the expected changes as well as of planned activities to adapt to the changes,
  - notify SA of any unexpected change immediately after its occurrence.

Additionally, a client <u>carrying out certification</u> shall undertake to:

- define the policy and procedures on action for the case of suspension, withdrawal of accreditation, or when the accredited CAB terminates its activities, in particular the rules and procedures in relation with the validity of previously issued certificates or statements.

Additionally, a client carrying out management system certification shall undertake to:

- make available, by 31 January of each year, the data needed to define indicators for the previous calendar year, including: the number of accredited certificates in force at the end of the year; the number of auditors; the number of accepted transfers from another certification body; the number of late audits; and the number of audit days performed. The data shall be reported separately for each certification scheme, and separately by countries in which certification is being performed;
- not assess conformity to the requirements of standards or other regulations which are intended to assess the competence of CABs (e.g., the standards indicated under Clause 4 hereof);
- inform SA of the reasons for termination in the case of termination of cooperation with a foreign legal entity who, on his behalf and for his accreditation, carries out and/or conducts the activities of management system certification.

Additionally, a client <u>carrying out verification of greenhouse gas emission reports</u> shall undertake to:

- submit by 15 November of each year:
  - the plan of verifications for the next period, including information on the planned time and place of the verifications,
  - the address and contact details of the aircraft managers or operators whose emission or tonne-kilometre reports are subject to verification,
  - the names of verification team members and the scope of accreditation to which the activity of the aircraft manager or operator belongs,

and to communicate, by 15 January of the current year, all the changes occurring in the verification plan.

Additionally, a client <u>carrying out environmental verification</u> shall undertake to:



- communicate to SA their intention to carry out environmental auditing at least 4 weeks before each audit.

# 2.4 Legal status of clients in accreditation procedure

A client or a contracting partner in accreditation procedure can be a legal entity or a sole trader, provided that the legal entity's or sole trader's organisation meets the requirements under clause 4, and that it is entered in the Business Register in the Republic of Slovenia. The legal status of the client and his registration for the activity in accordance with the *Decree on the Standard Classification of Activities* (RS OG, Nos. 69/07 and 17/08) shall be derived directly from the Business Register or from the instruments of incorporation published therein. In order to obtain or maintain accreditation, the client shall be registered for the activity *Technical Testing and Analysis* (71.2, 71.20 and 71.200, respectively), with the exception of obtaining or maintaining accreditation for the activities (86.909). Moreover, a medical laboratory shall hold a valid permission to operate based on Article 4 of the *Rules on requirements to be met by laboratories performing laboratory medicine tests* (RS OG, No. 64/04, 1/16, 56/19, 131/20 and 152/20), for the field of examinations for which they seek or maintain accreditation.

Accreditation certificate shall refer to the legal entity or the sole trader. The organizational unit holding the accredited activity shall be indicated in the accreditation certificate, when necessary, to make distinction between the accredited CABs.

The organisation of the conformity assessment activity within the legal entity or the sole trader shall be laid down in its instrument of incorporation, its statutes or some other general instrument, adopted by the competent authority of that legal entity or the sole trader. The definition of the organizational or business unit shall be derived from the internal structure of the legal entity or the sole trader's organisation.

SA will conclude with the client contracts for individual fields of accreditation, as stated in clause 3 and/or Annex 2. SA may, upon client's request, conclude with him several contracts for the same field of accreditation. In such case, the client shall bear all the costs relating to obtaining or maintaining two or more accreditations.

In accordance with last indent of paragraph one of sub-clause 2.3, the client shall notify SA of any change in his legal status. In the case of a status change involving universal legal succession, SA will issue a new accreditation certificate and annex thereto and propose to conclude a new Contract with duly coordinated data of the client.

In changes in which legal succession is not determined (transfer of activities or part of the assets to another legal entity – e.g. sale of a department, whereby the old legal entity remains registered), conclusion of Contract between SA and the acquiring legal entity as well as transfer of accreditation to the new client along with continuity of the accreditation procedure will only be possible when the former client in accreditation procedure and the acquiring legal entity conclude a mutual agreement which makes it clear as to who has renounced the accreditation Contract with SA and who accepts the new obligations, and provided that the acquiring legal entity meets all the requirements for accreditation. The provisions of this paragraph shall equally apply to a sole trader. In such cases the client shall normally submit a new certificate of non-conviction of legal entity (or – in the case of sole trader –



Transfer of certificate to another legal entity shall be charged as extension according to the SA rates (S10).

# 2.5 Language of procedure

Slovenian shall be the language used during the accreditation procedure. In the case when SA employs foreign assessors in the procedure, English or any other foreign language may be the language of communication with them, provided that the client does not oppose to it.

SA shall set up an assessor team in such a way as to ensure undisturbed assessment, despite the partial use of a foreign language, so that the client can take part in the procedure without difficulties. When the client requests so, an interpreter or some other expert who can provide the translation must accompany the assessor team. In such cases, the assessments shall be prolonged accordingly. Any additional assessment time needed due to translation shall not be invoiced to the client.

Should any part of the client's documentation need translation because of the participation of foreign assessors, the client is bound to provide to SA the translations that he already has. SA will bear the costs of any additional translations and shall be the owner of such translations. If the client wishes to use these translations for his operations, he shall refund to SA the costs of translation.

When, within the accredited activity, the client operates in a language other than English, he shall provide for translation, when necessary, for carrying out the assessment.

When the client issues within the accredited activity reports/certificates referring to the accreditation in a foreign language other than English, they have to be issued in a bilingual version (foreign language/Slovenian or foreign language/English), and the contents of that report/certificate need to be written, beside that foreign language, also in Slovenian or English.

# **3** ACCREDITATION FIELDS OF ACTIVITY AND INTRODUCTION OF NEW FIELDS

The activities performed by SA are stated in *Annex 2* hereto and defined with respect to 5 levels of the accreditation activity structure laid down in the document *EA-1/06 A-AB:2022, EA Multilateral Agreement – Criteria for signing – Policy and procedures for development.* 

SA shall determine the needs for introduction of new fields based on the needs expressed by the state authorities, owners of schemes and other interested parties, and on the basis of collaboration with SA's clients, and on the basis of applications for accreditation received.

SA shall plan the introduction of new fields of activity taking into account the available financial and human resources.

The SA Board shall make the decision as to introduce a new field at the second, third or fourth level of the accreditation activity structure from *Annex 2*, whereas the SA Director may decide on introduction of a new field at the fifth level.

After receiving an application for accreditation for a new conformity assessment scheme, which the owner of the scheme wishes to become international, SA shall check with EA whether that scheme is already approved and already has appointed home accreditation body (hAB). When the scheme is not



approved yet and the hAB has not yet been appointed in the case of a national scheme, SA shall carry out an accreditability evaluation procedure for the new scheme. SA shall conclude appropriate arrangement with the owner of the scheme. Scheme evaluation will be charged in accordance with the Rates (*S10*), taking into account the actual time spent according to the assessment day tariff.

The SA Board shall make the decision as to discontinue a field.

# 4 REQUIREMENTS FOR COMPETENCE

SA shall apply national, European and international standards as well as other regulations that govern the requirements for competence of conformity assessment bodies. SA shall define additional requirements for accreditation in its internal regulations, which govern the requirements for accreditation and rules of accreditation, which shall be maintained by SA as a public record, and a list of which shall be published on SA's website (<u>https://www.slo-akreditacija.si/accredited-cabs/sa-general-acts-governing-accreditation-requirements-and-accreditation-rules/?lang=en</u>). In addition, in its documents designated OA, SA shall define the policies and guidelines, or interpretations related to requirements for accreditation, and it can also use the documents of international associations for accreditation, and those of professional associations. SA shall keep a list of those documents on the website <u>https://www.slo-akreditacija.si/?post\_type=lpdocument&s=d05-10&lang=en</u>.

The above-mentioned term "standards" shall include all standardization documents, as defined by the applicable *Standardization Act*.

In its accreditation procedures, SA shall assess competence of different types of CABs to the requirements, which are defined in *Annex 3* hereto.

When, within the scope of conformity assessment procedures, the accredited CAB performs other types of conformity assessment, the relevant requirements to that other type of conformity assessment shall also be used in the assessment (e.g. the requirements for testing and calibration laboratories shall be used in accreditation procedures for inspection and certification bodies, when the respective inspection or certification body performs testing or certification as basis for decisions on inspection or certification).

When accreditation is performed for notification purposes, the accreditation scheme shall be defined in the regulations and guidelines issued by the relevant state authority, taking into account *EA-2/17 M*:2020 – *EA Document on Accreditation for Notification Purposes*.

# 5 ACCREDITATION PROCEDURE

The accreditation procedure shall run as provided herein. The individual steps of the accreditation procedure are shown in the "Accreditation procedure flowchart" in *Annex 1* hereto.

#### 5.1 **Pre-application contacts**

General information about SA and about the accreditation procedure shall be available on SA's website (*www.slo-akreditacija.si*). At the client's request, SA shall provide him with the general information regarding accreditation, the criteria and the procedures. The information can be provided by telephone, in writing or personally in SA's head office.



Prior to filing an application, the client and SA shall meet at a briefing meeting, where the client shall describe to SA his status and the activities he performs; the activities for which he seeks accreditation; and outline the scope of the accreditation sought. At the meeting, SA shall inform the client of the relevant document which defines the requirements for competence and, when necessary, of the guides and interpretation documents that are essential to the client's field of activity; give a short presentation of the accreditation procedure; answer the client's general questions regarding the interpretation of individual requirements; or provide additional explanation of the accreditation procedure.

Based on the data acquired at the briefing meeting and any other information gathered, SA will determine whether the activity performed by the client may be subject to accreditation, and whether there are any obstacles hindering the start of the accreditation procedure.

Should SA determine that the client's activity could not be subject to accreditation, it shall communicate this to the client.

When SA has not established an accreditation scheme for the desired field yet, it shall inform the client of the actual state of affairs and of the expected term within which SA would establish the scheme, and when the accreditation procedure could start.

# 5.2 Application for accreditation and its examination

The accreditation procedure shall start upon the client's filing of an application for accreditation and sending it in on a special application form (hereinafter called "the application").

In his application for accreditation, or attached to it, the client (hereinafter called "the applicant") shall provide the following information:

- general data (name or trade name and address, legal status, activity, position in the organisation and relationship with any other organisational units, technical and staff capacities, sites at which the activities are being performed;
- (only when first applying for accreditation and not in the case of extension of scope and for applicants that do not belong to state authorities) certificate of non-conviction for legal person (or in the case of sole trader certificate of impunity of natural person) and extract from the Criminal Record to certify that the applicant has not been finally held liable for committing an offence relating to the fields of activities applied for;
- an exact and clear specification of the type, field and scope of the accreditation sought, in accordance with the rules set by SA, and in such a way as to make impossible any misleading as to the type, scope and field of accreditation;
- statement of agreement to the following conditions for implementing accreditation procedure, that:
  - the applicant has an operating management system in place, which enables him to meet all requirements of the relevant document containing requirements for competence;
  - the management system is documented to the extent required by the relevant document containing requirements for competence;
  - taking into account the requirements of the relevant document containing requirements for competence, at least:
    - one internal audit has been carried out in the complete scope, and
      - one management review has been carried out;



the applicant is performing all the conformity assessment procedures stated in the application;
the applicant will continuously fulfil the requirements for accreditation and his obligations to SA concerning accreditation.

After receiving the application, SA will issue to the applicant an invoice for the application fee according to SA's rates. SA will examine the application after receiving the payment of the application fee, and based on the application and all previously gathered information (including that obtained at the briefing meeting), SA will determine whether the conditions for concluding a Contract are met, and define the scope of accreditation for which an initial assessment will be carried out.

Should SA find out, while examining the application or during any stage until grant of accreditation, that the applicant has been convicted of a criminal offence or found liable for committing an offence related to the scope of accredited activities, or that the applicant deliberately furnishes false information or conceals information, SA will refuse the application or stop the procedure.

Should the examination of the application take longer (e.g. when an extension of SA's field of activity or acquisition of competent assessors would be needed), SA shall inform the applicant of that and of the intended further course of the procedure.

Should the applicant, prior to signing the Contract, withdraw the application for the complete scope of accreditation, the person authorised for signing the Contract shall notify SA to that effect. Based on this information, SA will make a decision to stop the accreditation procedure.

Should the applicant, prior to signing the Contract, withdraw the application for part of the scope of accreditation, he shall file a new application for accreditation, for which SA will not charge the client.

# 5.3 Deciding on the start of the procedure and signing of the Contract

Should SA decide that the accreditation procedure cannot be started, it shall notify the applicant to that effect and state the grounds and circumstances for making such a decision.

When SA finds that the accreditation procedure can start, it shall send to the applicant a "Contract on establishing and maintaining accreditation" to sign. SA will conclude the Contract when the following conditions have been met:

- 1. by the applicant:
  - that the applicant has completed the application in full, and paid the fee according to SA's rates;
  - that the applicant agrees to the conditions for carrying out accreditation as given in the application;
- 2. by SA:
  - that SA has in place an accreditation system for the field for which the applicant has filed the application;
  - that SA has at its disposal the necessary resources for the performance of the accreditation procedure, in particular properly competent assessors.

The "Contract on establishing and maintaining accreditation" shall be a standard-form contract, and shall include:

- the applicant's particulars (trade name or name, registered address, registration number, tax number, bank account, name and surname of the legal representative),
- subject of the Contract,



- rights and obligations of the contracting parties,
- type of activity, price and payments,
- manner of enforcing amendments to the Contract,
- duration and reasons for termination of the Contract,
- disclaimer of SA's liability for the conformity assessment activities carried out by the applicant,
- legal remedies,
- provisions referring to safety and health during the performance of assessments,
- the manner of resolving disputes,
- anti-corruption clause,
- manner of enforcing the Contract, and
- the scope of accreditation for initial assessment given in an annex to the Contract.

The Contract shall be concluded for an unlimited period of time and shall apply to the establishment of accreditation and its maintenance. The applicant shall have the right to terminate the Contract at any time; however, he shall bear all the expenses incurred so far in the accreditation procedure.

Should the applicant, after having filed an application, not conclude the Contract for reasons on his side, he shall not be eligible for refund of the application fee.

Should the signature of the Contract, for reasons on the applicant's side, not have taken place within 1 (one) year of receipt of application, SA shall make a decision to stop the accreditation procedure and serve the decision to the applicant.

The applicant may withdraw from complete scope applied for at any time before the grant of accreditation, in which case the applicant's legal representative shall make a written statement of withdrawal. Based on this statement, SA shall make a decision to stop the accreditation procedure, and the Contract on establishing and maintaining accreditation shall automatically be deemed terminated.

The applicant may withdraw from a part of the scope applied for at any time before the grant of accreditation by making a written statement of partial withdrawal from the scope applied for, stating the part of the scope from which they withdraw.

SA shall have the right to terminate the Contract should the applicant not fulfil the obligations thereof but shall previously caution the applicant of the irregularities and give him sufficient time to remedy them. Should the applicant not remedy the irregularities within the given time limit, SA shall be entitled to terminate the Contract for reasons on the side of the applicant.

SA shall also have the right to terminate the Contract should it not have been possible, for reasons on the side of the applicant, to proceed with the procedure within 1 (one) year of signature of the Contract. In such a case SA shall send to the applicant, by registered mail with return receipt, a notice about its intended stopping of the accreditation procedure, including a warning of automatic termination of the Contract on establishing and maintaining accreditation. Should the applicant, within 30 days of the date of posting the notice, not reply to it or make a statement to the effect that they will be ready for the assessment within 2 months at the latest, SA shall make a decision to stop the accreditation procedure and serve it to the applicant.

The provisions of this clause shall apply for the time until the grant of accreditation, while the provisions of clauses 5.6 and 6 shall apply for the time after the grant of accreditation.



#### 5.4 Pre-assessment

SA will carry out pre-assessment upon request by the applicant.

SA shall notify the applicant of a pre-assessment visit to be paid by the lead assessor to the applicant's head office and/or the sites where the activities subject to accreditation are performed. During the pre-assessment visit, SA shall find out whether the conditions for an initial assessment are met, check that the scope of activities stated for initial assessment has been unambiguously defined, and collect any other information relevant to the planning and organisation of the initial assessment.

Should the assessor find any deficiencies in system solutions and work organisation, or in the performance of the activities for accreditation, such that make it impossible to carry out an initial assessment, or such that the nonconformities found during the initial assessment would certainly require repetition of the initial assessment in total, he shall inform the applicant to that effect.

After the conclusion of pre-assessment, the assessor shall make a written report of which the applicant shall receive a copy. In his report, the assessor shall point to any observed deficiencies in fulfilling the requirements for accreditation. The report shall include a proposal as to how to proceed with the accreditation procedure.

If the report contains an arrangement between SA and the applicant to suspend the procedure for the time until the applicant has implemented the activities specified in the arrangement, SA shall wait for the applicant's notice before resuming the procedure. Should the applicant, within a reasonable time (approximately one year) not provide to SA evidence of fulfilment of the conditions for resuming the procedure, SA shall give a warning to the applicant and invite him to communicate to SA the time limit within which he will meet the arrangement. Should the applicant not communicate the time limit, or should this be unreasonably long, SA will send to the applicant by registered mail with return receipt a notice about its intended stopping of the accreditation procedure, including a warning of automatic termination of the Contract on establishing and maintaining accreditation. Should the applicant, within 30 days of the date of posting the notice, not reply to it or make a statement to the effect that they will be ready for the assessment within 2 months at the latest, SA shall make a decision to stop the accreditation procedure and serve it to the applicant.

In the case of finding, during pre-assessment, any essential deficiencies referred to in paragraph (3) above, and no arrangement has been made with the applicant as to suspension or termination of the procedure at the conclusion of the visit, SA shall notify the applicant to that effect and suggest suspension of the procedure until the deficiencies have been remedied, or termination of the procedure and termination of the Contract. Should the applicant insist on carrying out the initial assessment despite SA's warning, the procedure will be resumed by initial assessment according to the rules of procedure.

#### 5.5 Initial assessment

An assessor team shall carry out the assessment. SA shall appoint such assessors and experts into the assessor team, whose expertise fully covers the scope of activities being subject to accreditation procedure. The assessment shall include examination of the management system documentation, its implementation and efficiency, as well as witnessing of the performance of the activities comprised within the scope of accreditation, and review of the resources. The assessment shall include all the activities necessary for the assessors to establish the fulfilment of the requirements in all fields within



The assessor team shall perform the assessment by taking into consideration the documents in force on the day of assessment.

SA shall plan initial assessments according to the order of receiving applications for accreditation, except for those conformity assessment activities recognised as urgent in given specific circumstances, and in relation to which the SA Board makes a decision on priority treatment. SA shall notify the applicant in writing, by registered mail with return receipt, of the composition of the assessor team, of the expected duration, the price and the expected dates of assessment at the applicant (notification of assessment), at least 15 days before the start of the assessment.

SA shall also inform the applicant of the expected scope and course of the assessment (programme). For the purpose of training the assessors or supervising their work, SA may include observers and/or assessor candidates or their supervisors in the assessor team. SA may also include assessment observers for the purpose of conducting internal audits within SA, or within the framework of international peer evaluation, or for other reasonable grounds.

At a closing meeting, the assessor team shall present the nonconformities found or any derogation from the requirements for accreditation, upon which the responsible persons of the applicant shall propose actions to eliminate the nonconformities and the time limits for the implementation of individual actions, when this has not already been done in the course of the assessment. The lead assessor shall confirm the team's agreement with the suggested corrective actions. The assessor team shall also decide whether the implementation of the corrective actions will be checked for compliance through examination of the documentation or through additional assessment. The time limit for implementation of individual action shall be laid down by the assessor team in agreement with the applicant; but it shall exceed 6 months in the case of initial assessment.

In exceptional cases, when defining corrective action at the closing meeting would not be practicable or reasonable (e.g. for nonconformities found within the framework of witnessing an audit/verification, or when an in-depth analysis would be necessary of the reasons of nonconformity, risks or possibilities for taking action, assessment carried out by reviewing the documents or remotely), and when the assessor team agrees to it, the auditee may (within an agreed time limit typically not longer than one week) subsequently prepare proposals of corrective actions and time limits for their implementation, and send them to SA in writing. The deadline for reporting on implemented actions shall not change by this (6 months in the case of initial assessment, 2 months since the last day of individual visit performed, or two months since the last day of individual witnessing of audit/verification).

The assessor team shall also summarize the course of the assessment and the general conclusions, and point out individual particular circumstances or arrangements, as necessary. At the closing of the assessment the applicant will normally receive an assessment report including a collection of nonconformity reports. In special cases (e.g. assessment to be carried out in several parts; complex assessment including a large number of assessors; parallel assessment at different sites), SA will provide the assessment report to the applicant subsequently, but generally not later than a week after the conclusion of the assessment. Should the findings in that report differ from those presented in writing



or verbally at the closing meeting, SA shall include in the report an explanation of or reasons for the differences.

After the closing of the assessment visit, the applicant shall send to SA, within an agreed time, a report of implemented corrective actions and attach to it any documents in support of the statements given in the report. A proposal for a new scope of accreditation shall also constitute a part of the report, should this be necessary based on the findings of the assessment.

SA shall send the report with the corresponding attachments to individual members of the assessor team.

The assessor team shall examine the reports and – in case of any doubt – they may request additional written explanations and evidence of implemented corrective actions. The applicant shall provide these within 2 weeks of receipt of the request. Supplements may normally only be made once.

When determined so at the assessment visit, or when the examination of the documentation shows that the necessary information on the appropriateness of implementation of the actions cannot be acquired from the documents alone, an additional visit shall be carried out to review the actions.

After the conclusion of the review, the assessor shall prepare a report of the review of the actions, and a recommendation for decision on accreditation. The lead assessor shall then give his/her recommendation taking into consideration the recommendations of all the other assessors.

Minor assessor tasks in the context of individual assessment, which concern specific technical fields, may be performed by merely examining the documentation, when possible (e.g., assessment of internal calibration procedures). In such cases, the assessor shall carry out the assessment by examining the documentation sent in for this purpose by the applicant. Other members of the assessor team shall be informed of his/her findings and shall take them into consideration when performing the assessment. Should the assessor find any nonconformities, these shall be treated according to the procedure defined under 5.7.1.

Should the assessor team by merely examining the documentation provided for the purpose of assessment, or based on other information, unambiguously identify any key shortcomings or obstacles to carrying out the assessment, SA shall call the client and propose consensual postponement of the assessment until the client informs it of having eliminated the identified shortcomings or obstacles. Any costs already incurred shall be borne by the client. Should the client insist on carrying out the assessment according to the initial plan, the provisions of next paragraph shall be complied with.

Should the assessor team find, during the assessment, that the conditions for carrying out the assessment have not been met (e.g., the applicant not being ready for assessment, or not providing SA access to all the information necessary to determine fulfilment of the requirements), they will suspend the assessment and issue a report with recommendation as to the manner of resuming the procedure, on the basis of which SA shall adopt one of the following decisions:

- to resume the assessment procedure,
- to suspend the accreditation procedure and define the conditions and manner of resuming it, or
- to terminate the accreditation procedure and refuse to grant accreditation.

Should the assessor team find out, during any stage of assessment, that they cannot acquire all the evidence on meeting accreditation requirements within the scope of the assessment activities carried



out and those anticipated (see 5.7.1.4 for examples), or that the implemented actions cannot be assessed for compliance through examining the documentation, and this had not been agreed upon at the assessment, they shall recommend an additional assessment to be carried out.

Should the assessor team find out, during any stage of assessment that, for reasons on the side of the applicant, they are unable to acquire all evidence of meeting the requirements for accreditation within the scope of the assessment activities carried out and those already foreseen, and that evidence cannot be acquired within a reasonable time, they shall recommend SA to stop the accreditation procedure.

When initial assessment needs to be repeated or additional assessment must be carried out, this shall only be performed once. Should grant of accreditation not be possible after the conclusion of such assessment, the accreditation procedure shall be stopped, and the Contract shall be deemed terminated.

When SA interrupts or stops an accreditation procedure or does not carry out or postpones an already agreed assessment or part thereof for reasons on the side of the applicant, the applicant shall defray all the expenses incurred so far, as well as any expenses that may arise as a consequence.

# 5.6 Decision on grant of accreditation

After the assessment procedure has been concluded, SA will adopt a decision to grant accreditation, if it can be derived from the assessor team's reports and recommendations as well as other information available to SA, that the applicant fulfils the accreditation requirements.

The accreditation shall apply until withdrawn, except for verifiers on greenhouse gas emission reports where the accreditation is granted for a period of up to maximum 5 years.

SA shall issue an accreditation certificate with annex comprising the scope for which it has found the applicant to meet the conditions for accreditation. In the accreditation certificate SA shall make a statement as to the accredited CAB's competence by referring to the relevant standard or any other normative document which lays down the requirements for competence of CABs. Annex to accreditation certificate shall specify the scope of accreditation, including specification of conformity assessment sites and activities, as well as the data on validity of accreditation. Rules regarding the definition of scope of accreditation are laid down in the document *S14* and its annexes for individual fields of accreditation.

Through the grant of accreditation, the applicant shall obtain the status of accredited CAB, and thereby the right and duty to make reference to accreditation and to use the accreditation mark together with his identification number; the accredited CAB shall use the accreditation mark in compliance with SA's requirements as laid down in the document *S05*.

SA shall maintain and allow public access to the information about the holders of accreditations at the SA head office and on its website, where the title or name and registered office of the accredited CAB, its identification number shall be indicated, and access to a detailed description of the scope of accreditation in annex to accreditation certificate shall be provided.

When the applicant has not remedied the nonconformities through corrective actions, or the applicant has not allowed the assessor team to acquire the requested evidence and/or explanations as to his meeting of the requirements for accreditation, accreditation cannot be granted, and SA will make a decision to refuse accreditation.



After the time limit for filing an appeal against the decision to refuse accreditation has expired, or in the case of appeal against the decision to refuse accreditation after the decision on refusing the appeal has been served, the decision to refuse accreditation shall be final. On that date the Contract on establishing and maintaining accreditation shall also automatically expire.

# 5.7 Maintenance of accreditation and surveillance of the work of accredited CABs

In order to maintain the accreditation obtained, the accredited CAB shall permanently comply with the accreditation requirements.

#### 5.7.1 Assessments

For the purpose of controlling the work of accredited CABs after having obtained accreditation, SA shall carry out regular surveillance assessments and reassessments, and – where applicable – also assessments for extension of scope of accreditation, extraordinary (announced or unannounced) assessments, additional assessments and assessments including a foreign accreditation body as subcontractor.

SA may carry out assessments by visiting the CAB, remotely, or through examining the documentation.

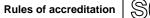
Assessments shall be carried out according to the procedure under 5.5, except where otherwise defined herein.

#### 5.7.1.1 Surveillance assessments and reassessments

After the initial assessment, SA shall undertake ordinary surveillance assessments. The interval between two ordinary surveillance assessments shall typically be 12 months. An interval is considered to be the period of time between the beginning of an assessment visit and the beginning of next one. SA shall make a fourth surveillance in terms of reassessment after the lapse of 4 years since the initial assessment. One accreditation cycle shall consist of three successive surveillances and a reassessment. An accreditation cycle shall last maximum 5 years. It shall start with the beginning of organizing the first ordinary surveillance assessment in the cycle, or with the decision – should this not have already been made at the beginning of organizing – and end with the decision after reassessment.

The scope of ordinary surveillance assessments should be such as to ensure that each ordinary surveillance assessment involves checking the client's continuous compliance with the accreditation requirements, and that, within one accreditation cycle each accredited activity is assessed as a whole at least once, and all the sites at which the conformity assessment activities are performed are assessed at least once. In reassessment, the same as in the initial assessment, a comprehensive review of compliance against all accreditation requirements shall be made, while in interim ordinary surveillances, only a part of the management system elements shall be chosen each time for a comprehensive review, so that all the elements are comprised in three successive ordinary surveillances. Also, information on the performance of the accredited CAB from previous assessments and other sources shall be taken into account in planning and carrying out assessment.

After the first reassessment, SA may extend the interval between individual ordinary surveillance assessments when it considers that that such extension would not diminish its confidence in the work of the accredited CAB. In such a case, the interval between two ordinary surveillance assessments can be extended to 15 months. Exceptions are schemes which explicitly indicate the surveillance interval (e.g., quality management system certification in production of medical devices in compliance with *SIST* 





*EN ISO 13485*; certification of organic production and processing; and GHG emission reports verification).

Individual interval between two ordinary surveillance assessments may be prolonged up to maximum 18 months, provided that there are good reasons for that, but the prolongation is normally compensated in next assessments in such a way that the duration of interval between two reassessments is approximately 5 years or 4 years when a twelve-month interval is specified for performance of two successive regular assessments.

When, due to suspension the above specified surveillance intervals have been exceeded, the lag shall be compensated, if possible, within the same accreditation cycle, taking into account, *mutatis mutandis*, the minimum interval between ordinary assessments (minimum 6 months).

The client shall remedy, within the shortest possible time, the nonconformities found during surveillance assessments or reassessments that could critically and directly affect the results of his work. He shall not be allowed to perform the accredited activity affected by the nonconformities until these have been remedied. All the nonconformities shall be remedied within appropriate time limits approved by the assessor team upon proposal by the accredited CAB.

Regardless of the time limits specified in the previous paragraph, the client shall report to SA about the implementation of all corrective actions at the same time, but within 2 months after the assessment at the latest.

#### 5.7.1.2 Extraordinary assessments

When essential changes take place in the client, or when any other information would raise doubts as to the proper performance of the client, SA may undertake an extraordinary assessment between the ordinary ones.

SA will undertake an extraordinary assessment when it has at its disposal information showing disrespect of accreditation requirements or raising doubt as to the competence of the accredited CAB in question, or indicating suspicion of data concealment or falsification or any other fraudulent conduct.

Reasons for extraordinary assessment can be:

- important changes in the accredited CAB,
- extraordinary addressing of extension of scope,
- suspension of accreditation,
- complaint against the work of the accredited CAB, and
- information on the work of the accredited CAB obtained by SA from other sources.

SA will normally announce the extraordinary assessment, save exceptionally in procedures of addressing information on the work of accredited CABs, complaints against the work of accredited CABs, or in the case of changes in accredited CABs that could have an important impact on the accredited activity. In such cases extraordinary assessment or part thereof can be carried out unannounced. The costs of extraordinary assessment shall be charged in accordance with the provisions of Article VII of the document S10.

The written notification to the client on the composition of the assessor team, the price and the expected date of assessment (notification of assessment) for extraordinary assessment may be sent by SA by



registered mail with return receipt within a shorter time limit, i.e., at least 8 days before the beginning of extraordinary assessment. For unannounced extraordinary assessments SA shall not send the notification in advance but shall hand it over to the client on the day of extraordinary visit or e-mail it with delivery certificate and send it by ordinary mail on the date of beginning of extraordinary assessment of documentation, or remotely. The assessor team shall in this case normally consist of assessors and/or experts who have already assessed the client, or they should be appointed so as to ensure their impartiality. In the case of unannounced extraordinary assessment, objection to the composition of the assessor team shall not suspend performance of the assessment.

The time limit for reporting on the implemented actions shall be specified by the assessor team, depending on individual situation at the client, but shall not be longer than 2 months after carrying out extraordinary assessment.

5.7.1.3 Assessment for extension of scope of accreditation

An accredited CAB wishing to extend or change the scope of accreditation shall send to SA an appropriate application for extension of scope. The accredited CAB shall submit the application for extension in accordance with the requirements of the document *S14 with annexes* for all changes of the fixed scope of accreditation and for those changes of the flexible scope of accreditation that lay outside the defined limitations. The provisions of sub-clauses 5.2 and 5.3 shall apply, *mutatis mutandis*, to examination of the application for extension.

SA will conclude with the accredited CAB a corresponding annex to the Contract on establishing and maintaining accreditation. As a rule, SA will carry out assessment of the extension or change within the scope of an ordinary assessment (surveillance assessment or reassessment).

SA must receive an application for extension in time to be able to conduct the relevant assessment during the course of an ordinary assessment. This is typically 3 months before the intended ordinary assessment, when a minor extension of an activity related to the accredited activity is involved (so that no additional technical assessors will be needed), or 6 months when a major extension is involved, when the extension goes beyond the technical field of the accredited activity, or extension to a new organizational unit or site.

Assessment for an extension can also be conducted outside the term of an ordinary assessment, all by observing the order of applications.

In exceptional cases, extensions may be made outside the order, when SA considers them to be urgent (e.g., modifications of normative documents with short transitional period, so that extension according to regular procedure would not allow further performance of the accredited activity).

The same treatment can also apply to extensions which are considered as urgent by the accredited CAB. Normally, the accredited CAB may use the possibility of extraordinary treatment of extension once in the accreditation cycle at the most.

Minor changes to the scope of accreditation (e.g., improvement of measurement uncertainty, expansion of measuring range, minor changes in conformity assessment procedures) can exceptionally be assessed by the assessor team in the course of ordinary assessment, even if they have not been announced beforehand, when the team find that this could be done without having an essential impact on the schedule and contents of the assessment, and if they find themselves competent to do so. If the

client wants to make sure that such minor changes of the scope of accreditation are assessed in the course of ordinary assessment, they shall submit an application for extension prior to the assessment.

When a minor change or amendment of the accredited activity is involved, the extension can in particular cases be assessed through examining the documentation only. In such a case, after signing an annex to the Contract on establishing and maintaining accreditation, SA will carry out the assessment according to the procedure defined under 5.7.1.5.

Should the assessor team find out during the assessment of extension that the conditions for carrying out the assessment have not been met (e.g., the client is not ready for assessment, or the client has not sufficiently implemented the methods/procedures being the object of extension), they shall act according to the procedure defined under 5.5.

Addressing of the nonconformities found and deciding as to extend the scope of accreditation shall proceed in the same way as in surveillance assessment or reassessment, and normally, simultaneously to surveillance assessment or reassessment.

When SA decides to extend the scope of accreditation, it shall issue a new annex to the existing accreditation certificate.

The surveillance of an extended scope of accreditation shall be performed together with the surveillance of the scope of accreditation held by the client before the extension.

#### 5.7.1.4 Additional assessment

Additional assessment shall be carried out when:

- assessor team member/s is/are unable to acquire, within the scope of the implemented and anticipated assessment activities, all the evidence of compliance with the requirements for accreditation (e.g., not sufficient time allotted for assessment; important specifics of the activity identified during the assessment that need special or additional treatment; presence of obstacles to carrying out the assessment due to which the assessment could not be carried out in the allotted time; assessor finds at random, while reviewing implementation of actions, new important (possible) nonconformities, therefore it is not possible to make recommendation for maintenance or grant of accreditation without clarifying the issue),
- assessment of conformity of the implemented actions cannot be made through examining the documentation (e.g., upon conclusion of assessment, it has been defined which nonconformities will need review of evidence of implementation through additional assessment; during postassessment activities, the need for additional assessment to review the implementation of actions has been established).

In terms of contents, additional assessment to review implementation of actions is focused on merely reviewing evidence of implementation of actions, therefore no new nonconformities shall be presented by SA to the client.

When, after the conclusion of additional assessment, it was not possible to acquire all the evidence of fulfilment of accreditation requirements, the assessor shall make a negative recommendation related to the object of the additional assessment, except in the case of additional assessment to review the implementation of actions, where single supplements to the evidence shall be allowed after the conclusion of the assessment.



#### 5.7.1.5 Assessment through examining the documentation

In particular cases (e.g., in order to address changes in accredited CABs, in order to address minor extensions of accredited activities, for the purpose of checking information about the work of accredited CABs and complaints about the work of accredited CABs), SA may carry out assessment through examining the documentation only. In such a case, SA shall normally announce the assessment and appoint an assessor. The accredited CAB shall send in the documents required by SA for the purpose of carrying out the assessment. After examining the documentation, the assessor shall draw up a report of the review. When nonconformities have been found, SA shall send to the accredited CAB reports of the nonconformities and a form for subsequent definition of actions and invite the accredited CAB to make an analysis and suggest – within one week at the latest – actions to remedy the nonconformities. When the client suggests actions, he is considered to agree with the contents of nonconformities; otherwise, he shall inform SA of his disagreement giving a suitable explanation. The accredited CAB shall send a report on the implementation of the actions within 2 weeks of receiving the assessor's agreement with the proposed actions. After examining the report, the assessor shall give a recommendation for accreditation. Should the documents sent in by the accredited CAB for assessment not enable the performance of assessment (e.g. being incomplete, untransparent), or should the assessor have found any nonconformities or potential nonconformities that require clarification with the accredited CAB, or should the client disagree with the nonconformities, or should the proposed actions be inadequate or their implementation unsatisfactory, the assessor shall draw up a report to that effect and make a corresponding recommendation (e.g. recommend an assessment visit, recommend refusal of extension).

#### 5.7.1.6 Remote assessments

In cases of emergency, or when circumstances do not allow carrying out assessment by visiting the site (e.g. when physical access in the CAB's premises is rendered impossible, or due to inaccessibility of the terrain or CAB's site due to emergency, adverse climatic events, disaster, pandemic, movement restriction, closure of borders, terrorism, or any other reason that does not ensure safety and/or health of assessor team members), and provided that all the preconditions have been met by the client, SA may carry out assessment or part thereof remotely, by using information and communication technologies that ensure suitable protection of data and information security. All types of assessment can be carried out remotely, except for initial assessments and extensions of conformity assessment activities which include new fields of activities, new organisational units or new sites. Initial assessment for which SA issues a special decision may be excepted.

Remote assessment contains, *mutatis mutandis*, all the assessment steps indicated under 5.5, which shall be adapted to the available ways of communication and remote exchange of information.

In order to be able to carry out remote assessment, SA shall normally obtain from the client, in addition to the standard set of documents, also additional documents and records. Based on review of the documents, SA may change the intended assessment programme or way of performance (e.g. postponement of the date, on-site assessment).

After the conclusion of the assessment, an assessment report with all reports of nonconformities found and actions agreed-on shall be e-mailed to the client and to the members of the assessor team. Acknowledgement of the receipt shall replace signatures.



When remote assessment has been carried out in the complete scope as required, the assessor team shall make recommendations, and SA shall make the decision on the basis of this assessment. On the other hand, remote assessment shall be considered as first part of surveillance, and decision on accreditation shall only be made when needed because of taking into account various changes (e.g. changes in requirements for accreditation; changes in scope or in accredited CAB's details). In either case, SA shall inform the accredited CAB of the indicative date and the way of proceeding with the assessment.

The costs of remote assessment using information and communication technologies shall be charged by applying the Rules on Price Formation for the Services Provided by SA (*S10*), in the same way as for usual assessments.

#### 5.7.2 Deciding on accreditation status

Each time after carrying out an assessment, SA shall re-decide on the status of the accreditation granted and on further procedure, and shall notify the client of its decision.

SA will confirm the validity of the accreditation, when it derives from the surveillance procedure that the accredited CAB meets the requirements for accreditation.

In the case of modifications to the scope of accreditation, SA shall make a decision to that effect and issue a new annex to existing accreditation certificate.

#### 6 TERMINATION OF ACCREDITATION

Should SA find out during surveillance procedures that the client does not meet the conditions for maintaining the accreditation, it will decide on termination of accreditation. Termination of accreditation may consist in suspension or withdrawal of accreditation.

Suspension of accreditation means that SA withdraws temporarily the accredited CAB's rights deriving from accreditation, with the Contract on establishing and maintaining accreditation remaining in force. Accreditation can be suspended for a maximum period of 6 months. Suspension of accreditation can refer to the complete scope of accreditation or a part thereof.

Withdrawal of accreditation means permanent withdrawal of accreditation. SA will withdraw the accreditation in its complete scope or a part thereof (reducing the scope of accreditation). Withdrawal of the complete scope of accreditation shall also mean automatic termination of the Contract, which shall expire on the date the decision on withdrawal of accreditation becomes final.

SA will make a decision to suspend accreditation when:

- it finds that the accredited CAB does not meet the requirements for competence, i.e. when due to the nature of the nonconformities found (e.g., if the nonconformities are significant and obvious and the accredited CAB has not started remedying them by himself), or if the same important nonconformities recur at several successive surveillance assessments, when it loses confidence in the client's management system, or when important changes have taken place in the accredited CAB (see 2.3), and it has not provided evidence of controlling them adequately; when the finding refers to a part of the accredited activities only, SA shall adopt a decision to suspend that part of the scope of accreditation;



- the accredited CAB does not fulfil other requirements for accreditation or obligations under 2.3 herein (e.g. promptly informing SA of changes; allowing access to the necessary information (e.g., not allowing the performance of full assessment or individual crucial parts of pre-assessment or assessment activities; not allowing access to the information necessary for carrying out the assessment); making reference to accreditation; meeting financial commitments);
- the accredited body proposes/requests suspension of accreditation in its complete or partial scope.

SA will make a decision to withdraw accreditation:

- in the case of findings under first two indents of the above paragraph, when the circumstances make it clear that, within 6 months, the accredited body will not be able to make changes that would restore confidence in its work;
- when, during the period of suspension, the accredited CAB has not been able to eliminate the nonconformities or other reasons for suspension, or has not allowed the assessor team to obtain the required evidence and/or explanations of its meeting the accreditation requirements;
- when the accredited CAB proposes/requests withdrawal of accreditation in its complete or partial scope;
- when the client has been convicted of a criminal offence, or found liable for committing an offence related to the scope of accredited activities;
- when the client has been found to deliberately furnish false information or conceal information;
- when bankruptcy or liquidation or any other termination proceedings have been imposed on the client, or when the client, who is a natural person, dies;
- when the validity of requirements for accreditation according to which the accreditation was granted has expired (and the transitional period if defined has ended).

When SA withdraws accreditation for reasons given under indent 4 above, the client may re-apply for accreditation as soon as the legal consequences of conviction in the case of offence have ceased, or within 3 years after the judgment has acquired the authority of a final decision, i.e. the decision by which the client was found liable for committing an offence related to the scope of accredited activities.

In the case of non-fulfilment of the requirements for competence, SA will make a decision on termination (suspension or withdrawal) of the accreditation within the scope of ordinary or extraordinary assessment, based on recommendations by the assessors. In particular cases, the decision on termination of the accreditation may also be made when SA receives information from other sources (e.g., from a complaint or from a relevant authority) about critical irregularities, which have clearly been proven.

When SA establishes non-fulfilment of other requirements for accreditation or obligations under 2.3 hereof, it will warn the accredited CAB in writing of its non-fulfilment of contractual obligations. Should the accredited CAB not meet these obligations by the time limit given by SA in its warning, SA may immediately decide to terminate (suspend or withdraw) the accreditation, of which the client must have been explicitly cautioned in the warning.

If the accredited CAB wishes his accreditation to be suspended or withdrawn, the client's legal representative shall make a written request for suspension or withdrawal of accreditation, stating the date on which the termination of validity should become effective. In a request for suspension or



withdrawal of a part of the scope of accreditation (reduction), the client shall clearly define the part of the scope the request refers to. In that case, SA shall make a decision on partial suspension or partial withdrawal (reduction) of the accreditation and send to the applicant an amended annex to accreditation certificate. When the request for suspension relates to the complete scope of accreditation, SA will make a decision on suspension of the complete scope of accreditation and send to the client an amended annex to accreditation certificate. When the request for suspension of the complete scope of accreditation and send to the client an amended annex to accreditation certificate. When the request for withdrawal relates to the complete scope of accreditation, SA will remove the scope of accreditation from the Catalogue of Accredited CABs on the effective date of the withdrawal, and on the same date, the Contract on establishing and maintaining accreditation will cease to apply.

SA will communicate to the client its decision to terminate the accreditation and provide an explanation of the decision. In its decision to suspend accreditation SA will also define the indicative date (month) of extraordinary assessment at which the fulfilment of the requirements for competence will be verified.

The decision on termination of accreditation becomes effective after the expiry of the deadline for appeal or, in the case of filing an appeal, with the serving of a decision on the appeal, except when the decision has been made upon the client's request, or in cases of emergency in the public interest. In cases of emergency in the public interest, an appeal shall not withhold the execution of the decision to terminate the accreditation.

SA shall publish the information on suspensions and withdrawals of accreditations on its website, and additionally also:

- In the event of suspension or withdrawal of accreditation of a certification body for deliberate infringement of the rules of accreditation procedure, or falsification of results, or deliberate misleading by the accredited CAB, or carrying out certification according to the requirements of standards or other regulations intended for assessing the competence of CABs, SA shall also communicate the information to the IAF Secretariat.
- Data on the suspension or revocation of accreditation of the verifier on greenhouse gas emission reports shall be submitted by SA to the national competent authority. When the verifier performs verifications abroad, this information shall be submitted to the competent authority and national accreditation body of the Member States in which the verifier performs the verification.
- In the event of suspension or withdrawal of accreditation of a certification body for organic production/processing, SA is obliged to inform of this the Ministry responsible for agriculture and Administration for Food Safety, Veterinary Sector and Plant Protection, and – in the case of certification in a third country – also the European Commission, including explanation of the reasons.
- In the event of withdrawing accreditation of a certification body for management systems, other accreditation bodies as well as the owners of the schemes concerned need to be informed.
- In the event of suspending or withdrawing accreditation of an environmental verifier, SA is obliged to inform of this the relevant authority of the Member State, in which the verifier is accredited, as well as the relevant authority and accreditation body of each Member State in which the verifier performs verifications.
- When SA suspends or withdraws accreditation for notification purposes, SA shall inform to that effect the Ministry responsible for notifications.



- In the event of suspending or withdrawing accreditation of a CAB which performs its conformity assessment activities abroad, SA shall inform to that effect the relevant local accreditation body(ies).
- When a certification body for management systems informs SA of its termination of cooperation with a foreign legal entity, who on its behalf and for its accreditation carries out and/or conducts the activities of management system certification, and states unfair or unethical conduct as a reason, SA shall inform to that effect the local accreditation body of the country in which the legal entity operates.
- When SA withdraws accreditation of a certification body or a verifier because it has been convicted of a criminal offence or found liable for committing an offence related to the scope of accredited activities, or it has been found to deliberately furnish false information or conceal information, SA shall inform to that effect the relevant authorities, accreditation bodies and scheme owners concerned.

During the effectiveness of the decision on suspension or withdrawal of accreditation, the client shall not use the accreditation mark or make any other reference to accreditation in relation with the activities under suspension/withdrawal.

The client should seek to implement the actions to eliminate the nonconformities or the causes of suspension as soon as possible.

When necessary, an extraordinary assessment shall be organized 2 months before the expiry of the suspension at the latest, in order to reconfirm fulfilment of the requirements for accreditation. When, due to suspension, ordinary assessment has been postponed, the extraordinary and at the same time ordinary assessment shall be organized 3 months before the expiry of suspension period at the latest.

The client shall provide to SA information on the implemented actions to eliminate the causes of suspension 1 month before the date (month) of extraordinary assessment defined in the decision. When, based on the information received, the performance of assessment to determine fulfilment of the requirements for accreditation is possible, SA will organize extraordinary assessment, and at the same time the ordinary assessment that has been postponed due to suspension. The deadlines for implementation of actions for individual nonconformities shall be adjusted so that the decision on restoring the validity of accreditation after suspension (termination od suspension) is feasible before the expiry of the suspension period.

Based on the results of that assessment, SA shall make its decision whether to restore the validity of accreditation or to withdraw it. When the non-fulfilment of other requirements for accreditation or obligations under 2.3 herein has been the reason for decision on suspension, and assessment is not required to determine the fulfilment of the requirements, SA will make its decision to restore the validity of accreditation after the suspension, or to withdraw it upon receiving the client's report. SA will make the decision on withdrawal also in the event that, based on the information received from the accredited CAB, or on the findings of the assessment, it is not possible to carry out extraordinary assessment to the extent needed to reconfirm the fulfilment of the requirements for accreditation.

Exceptionally (e.g., when due to *force majeure* or for other objective reasons, SA has not been able to carry out the necessary activities, although it clearly endeavoured to do so, or when for objective reasons the assessment could not be carried out in due time or the decision could not be made), SA may extend the suspension for the strictly necessary period, or up to 6 months at the most.



On the date the decision to withdraw the accreditation in its complete scope is final, the Contract on establishing and maintaining accreditation will automatically expire.

# 7 PERFORMING ASSESSMENTS ABROAD

SA shall ensure performance of assessments abroad only for clients registered in the register of companies or business register in the Republic of Slovenia, who perform conformity assessment activities from the (applied) scope of accreditation abroad. SA shall engage in a suitable way in the assessments the accreditation body of the foreign country (hereinafter called "the local accreditation body"). Where the local accreditation body is a signatory to the relevant EA MLA or IAF MLA or ILAC MRA agreement, SA shall ask local accreditation body to carry out the assessment as a subcontractor. When the local accreditation body refuses to carry out the assessment or is not a signatory to the MLA/MRA agreements, SA shall carry out the assessment and invite the local accreditation body to participate as an observer. Where possible and reasonable, the SA could include assessors from the local accreditation body in the assessment team. When necessary, SA shall also engage the local accreditation body in planning and/or carrying out assessments, in the case of assessing conformity assessment activities to which special national requirements apply.

Before being included into the scope of accreditation, the sites abroad (regardless of their legal status) at which the conformity assessment activities are performed, shall be assessed (the same as applies to the national sites).

When the assessment abroad is performed by SA, in addition to the time actually spent on the performance of assessments abroad, also the costs related to the assessments performed outside Slovenia shall be charged to the client, pursuant to Article VI of the document S10. When the assessment abroad is for SA performed by local accreditation body as its subcontractor, the client shall be charged with the labour costs of that local accreditation body according to the invoice issued by it, as well as the SA labour costs in the amount of half of the assessment day.

When the assessment abroad is performed by SA, SA may charge the client an advance payment of the costs, which the client shall settle before the beginning of the assessment, otherwise SA shall not perform the assessment abroad.

# 8 SURVEILLANCE OF ACCREDITED ENVIRONMENTAL VERIFIERS/LICENSE HOLDERS FROM OTHER EU MEMBER STATES (Regulation (EC) No 1221/2009, Articles 23, 24)

The surveillance of accredited environmental verifiers/license holders from other EU Member States, who perform the activity of verification against the European regulations in Slovenia, is a special case of surveillance of the work of accredited CABs.

Environmental verifiers wishing to perform the verification activities in Slovenia shall notify SA of their intention at least 4 weeks in advance of each verification.

They shall provide to SA, together with the "Notification for verifiers from other member states performing verification and validation activities in Slovenia" (form OB05-52, available on SA's website <u>http://www.slo-akreditacija.si/?post\_type=lpdocument&s=ob05-52</u>), at least the following information (Commission Decision (EU) 2016/1621):



- precise details of the environmental verifier's accreditation/license (accreditation body/licensing authority, date of accreditation/license, scope of accreditation/license, validity);
- details of individual members constituting the auditor team (competence, education and experience in the relevant technical field as well as in the field of environmental verification);
- measures taken to acquire knowledge of the Slovenian legislation;
- details of the environmental verification (time and place of the verification, data of the organisation and contact person, field of verification);
- envisaged way of communication with the personnel of the auditee organisation;
- details on meeting the requirements of ISO 14001 (report of certification audit);
- a copy of draft environmental statement;
- a copy of the verifier's report of preliminary review of the client's documentation and
- the environmental audit programme.

Upon examination of the application, SA will make a decision in advance and notify the verifier of the way of surveying his work.

The environmental verifier shall send to SA a verification report including the nonconformities found.

Should SA estimate that the environmental verifier does not perform in compliance with the requirements for accreditation/license of environmental verifiers, SA will send a report of the surveillance of the environmental verifier to the accreditation body who granted him the accreditation, and to the competent body in the Republic of Slovenia.

An accredited environmental verifier/license holder from another EU Member State who wishes to perform environmental verification in Slovenia, will be charged the application in addition to the actual time spent on surveillance.

#### 9 ADDRESSING INFORMATION ON THE WORK OF ACCREDITED CABs AND UNDUE REFERENCE TO ACCREDITATION

SA shall address the feedback or expressions of dissatisfaction obtained about the work of accredited CABs, as well as the feedback obtained on undue reference to SA accreditation.

SA may obtain this information formally, informally or accidentally, or receive for information purposes information/complaint, which has been formally addressed to some other institution, and which – at least in one aspect – also relates to the work of the accredited CAB or to undue reference to accreditation.

SA shall respond to the information obtained, when necessary, or take appropriate action in its relation, in accordance with the circumstances in each particular case.

The procedure of addressing the information obtained shall be conducted in such a way as to ensure non-discriminatory and confidential treatment. Because of protection of confidentiality, SA shall not disclose the way and the results of treating the information obtained on the work of accredited CABs and undue reference to accreditation, as well as other confidential information, unless it is bound to do so by a law, regulation or contract. In the case that SA is bound to disclose any confidential information related to the proceeding, SA shall inform the accredited CAB of disclosing confidential information to third persons, unless such informing is prohibited by law.



In the same way, SA shall also treat information arising from a complaint about the work of accredited CABs, even when the conditions for handling the complaint according to the procedure defined in 10.3.2 have not been met.

# 9.1 Information on the work of accredited CABs

The information obtained by SA on the work of an accredited CAB shall be considered by SA taking into account its relevance (risk of non-compliance with accreditation requirements, and in particular ability to ensure the validity of the results of the accredited activity) in the procedure of surveillance of the accredited CAB, as described in 5.7, whereby SA shall use the most appropriate way enabling it to conclude the treatment in appropriate time, taking into account the relevance of information.

SA shall address the information on the work of an accredited CAB within the framework of its competencies and other limitations (e.g., when the source of information does not allow disclosure of its identity).

# 9.2 Information on undue reference to accreditation

Information on undue reference to accreditation granted by SA, or undue use of the SA accreditation mark, may be obtained by SA from accredited CABs or from third persons.

When information on undue reference to accreditation relates to accreditation granted by another accreditation body, SA shall forward the information obtained to the competent accreditation body.

When SA obtains information on undue reference to SA accreditation, it shall first warn the infringer in writing about violation of the rules and request evidence of stopping the undue reference.

Where undue reference by an accredited CAB is the case, SA shall consider this in the surveillance procedure of this accredited CAB and define the most appropriate way of assessment, as indicated under 5.7. In cases where the accredited CAB does not demonstrate implementation of the necessary actions, SA will carry out the procedure for suspension of the accreditation.

Where undue reference of individual accredited CAB to accreditation by a third party is the case, SA shall inform this accredited CAB of the infringement and invite it to take appropriate action.

Where undue reference to accreditation in general, or undue use of the SA accreditation mark by a third party is the case, SA will also seek legal remedies against the third party.

# **10 HANDLING APPEALS, OBJECTIONS TO NOTIFICATION AND COMPLAINTS**

Clients in accreditation procedure shall have the right to appeal or to object against notification of assessment. The client may file an appeal when he does not agree with the decision on accreditation made by SA in accreditation procedure for the particular client. Handling of the appeal shall withhold the implementation of the accreditation procedure to which the appeal relates. The appeal handling procedure is defined in sub-clause 10.1.

The client in accreditation procedure may file an objection to notification of assessment when he disagrees with the conditions for implementation of the assessment as stated in the notification. The procedure of handling objections to notification is defined in sub-clause 10.2.



The client in accreditation procedure, or any other interested person not having the status of client in accreditation procedure, wishing to express their dissatisfaction in relation with the work of SA or the work of an accredited CAB, may file a complaint to that effect. SA shall address a complaint against the work of an accredited CAB according to the complaint handling procedure, when the complainant has previously addressed his complaint to the accredited CAB in question, but does not agree with the manner or the outcome of handling his complaint. When the complaint refers to the implementation of accreditation procedure, handling of the complaint shall not withhold the implementation of this procedure. The complaint handling procedure is defined in sub-clause 10.3.

# 10.1 Appeal

The client may file an appeal against a decision on accreditation made by SA in accreditation procedure for the client (hereinafter called "the appellant) when he does not agree with the decision. This includes all those decisions that hinder him from obtaining or maintaining accreditation.

# 10.1.1 Permissible object of appeal

An appeal shall be permitted against the following decisions made by SA during the accreditation procedure:

- decision on accreditation (e.g., refusal to grant accreditation, refusal to grant extended scope of accreditation, suspension or withdrawal of accreditation for the complete scope or part thereof),
- a decision to refuse an application for introduction of an accreditation procedure, or a decision to refuse an application for introduction of a procedure for extension of the scope of accreditation,
- a decision to refuse the performance of assessment,
- a decision on interruption or termination of procedure,
- on finding of nonconformities or refusal of a proposal for action, or refusal of implementation of action by the assessor team,
- other decisions made by SA, which impede the attainment or maintenance of accreditation.

#### 10.1.2 Receiving an appeal

The deadline for filing an appeal shall be 15 days from the date of serving to the appellant the decision against which he intends to file appeal. The provisions of the Act governing general administrative procedure shall apply as to the timeliness of appeal filing and counting of the time limits.

Upon filing an appeal, the appellant shall pay an advance fee for the appeal proceeding in the value of 1.5 assessment day according to the rates applicable on the date of filing the appeal.

The appellant shall send the appeal in writing, by registered mail and addressed to SA, or make it in person at the SA Secretariat, which will issue a receipt to the appellant.

In the appeal, the appellant shall indicate:

- that it is an appeal,
- details of the appellant and his legal representative or proxy,
- the case referred to by the appeal,
- reasons for appeal,
- grounds for appeal,



- whether or not the appellant wishes to attend the appeal hearing,
- appellant's or his legal representative's/proxy's signature,

and attach:

- evidence of his payment of advance fee for the appeal proceeding, and
- Power of Attorney, when the appellant is represented by a proxy.

SA shall acknowledge to the appellant the receipt of the appeal within 8 days of the receipt. Should the appeal not contain all the above-mentioned details and attachments, SA will invite the appellant to complete the appeal within 3 working days of his receipt of the invitation to complete the appeal. In the invitation, SA shall call the appellant's special attention to the consequences of not completing the appeal within the given deadline. If the appellant does not complete the appeal within the given deadline, the appeal will be considered withdrawn by the appellant.

#### 10.1.3 Addressing an appeal

SA shall conduct the appeal handling procedures in such a way as to ensure independent, nondiscriminatory and confidential treatment and its conclusion in a reasonable time.

During addressing of an appeal, the performance of the activities of the accreditation procedure being the object of appeal shall be interrupted. When the appeal is filed against a decision to suspend or withdraw accreditation, the appeal shall withhold the execution of the decision being the object of appeal.

After receiving the appeal, the SA Director will check it for timeliness, completeness and authorisation, and whether it is filed by the person so entitled. The Director will reject by a decision an appeal that is late, incomplete or unauthorised.

When the Director does not dismiss the appeal, and when upon reviewing the appeal he/she finds it to be substantiated, he/she shall make an appropriate decision regarding the object of the appeal; otherwise, the Director shall refer the appeal to the Appeal Commission to deal with it and inform the appellant to that effect. The chair of the Appeal Commission shall appoint a panel to conduct the procedure and address the appeal. All members of the Appeal Commission's panel shall be independent of the object of appeal. The Appeal Commission's panel shall study the complete documentation of the appellant and the corresponding documentation of SA referring to the object of appeal, and serve to the SA Board a report on the actual state, the technical and legal grounds, and a motion of decision on the appeal.

The appellant shall be entitled to attend the appeal hearing where the Appeal Commission's panel address the case and study documented evidence.

SA shall notify the appellant of the date of addressing the appeal at least 8 days prior the Appeal Commission's panel session. At the appeal hearing, SA shall allow the appellant to state facts and present evidence in support of his appeal.

Minutes shall be kept of the appeal hearing, which shall be signed by all members of the Appeal Commission's panel, the recorder, and the representative of the appellant, when attending the hearing. The appellant may, when reviewing and signing the minutes, make comments to the minutes, which shall be recorded and enclosed with the minutes. Should the appellant not wish to sign the minutes, this shall be noted in the minutes. The appeal hearing shall also be recorded. The chair of the Appeal



Commission's panel shall inform all those present that the appeal hearing is being recorded. The soundtrack of the recording of the appeal hearing may be destroyed by SA 6 months after the decision on the appeal became final.

# 10.1.4 Deciding on appeal

The decision regarding the appeal shall be made by the SA Board.

SA shall make its decision regarding the appeal as soon as possible, or at least within 60 days, or, in more complex cases – e.g., when a foreign expert needs to be engaged – within 90 days from receipt of a complete appeal application at the latest. When the appeal handling procedure takes longer to be concluded, SA shall inform the appellant of the indicative time frame within which the decision on the appeal will be made.

After the conclusion of the appeal handling procedure SA shall send to the appellant its decision on the appeal.

The decision on the appeal shall be final and may not be the object of a new appeal proceeding at SA.

When SA decides that the appeal is unjustified, the advance fee will not be refunded to the appellant.

When SA decides that the appeal is justified, SA will refund to the appellant the advance fee within 15 days of his receipt of the decision.

#### **10.2** Objection to notification of assessment

Should the client disagree with the appointment of one or more members of the assessor team, with the duration of the assessment, or with other conditions for performing the assessment, as defined in the notification, he may file with SA a written objection against the notification of assessment within 3 (three) days of receipt of SA's notification of assessment. In his objection, the client (hereinafter called "the objector") shall explain concretely and in detail and give grounds for his request. When the objection refers to the partiality of a member of the assessor team, the objector shall clarify and explain in his objection how or in what the conflict of interests of the member of the assessor team to whom the objection refers has been demonstrated.

SA shall decide on objection only in the scope of the objection assertions. The objector shall not attend the addressing of the objection.

When SA determines that the objection is justified and therefore a change of the conditions for performing the assessment is necessary, SA shall send to the objector a changed notification of assessment within 5 days.

When SA finds the grounds for objection unjustified, it shall confirm the original decision within 5 days of receipt of the objection and notify the client to that effect.

When SA finds the objector's grounds for objection against the composition of the assessor team filed during an unannounced extraordinary assessment to be justified, the results of the assessment in accreditation procedure shall not be considered and the assessment procedure shall be repeated.

There shall be no independent remedy against the decision on the objection.



#### 10.3 Complaint

Complaint is a written expression of dissatisfaction of an interested person to which a response by SA is expected. The content of dissatisfaction can relate to:

- the work of SA related to accreditation procedures or other SA's activities (e.g., the work of permanent SA employees, the work of SA assessors, various aspects of conducting accreditation and other procedures);
- the work of CABs holding SA's or any other accreditation body's accreditation (hereinafter: the work of accredited CABs).

SA shall conduct the complaint handling procedures in such a way as to ensure non-discriminatory and confidential treatment and its conclusion in a reasonable time.

In the case that SA is bound by law, regulation or contract to disclose any confidential information related to the handling of a complaint, SA shall inform the accredited CAB of communicating confidential information to third persons, unless such communication is legally prohibited.

#### 10.3.1 Complaint about the work of SA

The complainant shall send the complaint about the work of SA in written form, not anonymously, to SA, unambiguously stating and explaining the reason for complaint.

SA shall acknowledge to the complainant the receipt of the complaint within 8 days of receipt and communicate to him whether the complaint will be addressed according to the complaint handling procedure. Should the complaint not contain unambiguously stated and explained reason for complaint, or other information needed for the complaint to be addressed, SA will ask the complainant to provide additional information, stating the time limit by which the additional information shall be communicated to SA. Should the complainant not provide additional information within the given time, SA will not address such complaint.

Complaints about the work of SA shall normally be resolved within one month's time. However, when SA expects the complaint handling procedure to take longer, it shall notify the complainant in writing to that effect.

The SA Director shall notify in writing the complainant of the conclusions of the complaint handling procedure, and – when appropriate and admissible – indicate the implemented or intended actions. When there are several reasons for complaint stated in the complaint, the conclusions shall be given separately for each reason.

#### 10.3.2 Complaint about the work of accredited CABs

The complainant shall send the complaint about the work of an accredited CAB in written form, not anonymously, to SA, unambiguously stating and explaining the reason for complaint. The complainant shall attach to his complaint evidence of having previously addressed the complaint to the accredited CAB in question, including all the communication related to the accredited CAB's handling of the complaint.

SA shall acknowledge to the complainant the receipt of the complaint within 8 days of receipt and communicate to him whether the complaint will be addressed according to the complaint handling procedure.



When it is not clear from the complaint that it was previously sent to the relevant accredited CAB, SA will refer the complainant to this accredited CAB and invite him to re-address his complaint to SA should he consider the way or the result of handling his complaint by the accredited CAB to be inappropriate.

Should the complaint not contain unambiguously stated and explained reason for complaint, or other information needed for the complaint to be addressed, SA will ask the complainant to provide additional information, stating the time limit by which the additional information shall be communicated to SA. Should the complainant not provide additional information within the given time limit, SA will not address such complaint.

When the complaint relates to a CAB accredited by another accreditation body, SA will send the complaint to the competent accreditation body.

Complaints about the work of accredited CABs will be addressed by SA when the complainant makes it clear that he has already filed the complaint with the accredited CAB but does not agree with the way or result of handling his complaint; in any case, the information provided in the complaint will be considered by SA in the procedure of surveillance of this accredited CAB, as described in clauses 9 and 5.7 herein. SA will include the accredited CAB in question into complaint handling procedure, except when it finds, due to particular circumstances, that this would not be appropriate. SA shall not disclose the identity of the complainant in the procedure, should he not agree with the disclosure.

Addressing of complaints about the work of an accredited CAB is usually subject to circumstances beyond the control of SA. When the complaint handling procedure takes longer to be concluded (i.e., more than 1 month), SA shall inform the complainant to that effect and communicate to him the indicative deadline by which his complaint should be resolved, in which case SA may also prolong the deadline with justified reasons, and shall inform the complainant to that effect.

When appropriate and necessary, the accredited CAB to whom the complaint relates, shall give to the complainant a suitable response regarding the content of his complaint.

The SA Director shall notify in writing the complainant of the conclusions of the complaint handling procedure. In accordance with the confidentiality principle, SA may only communicate to the complainant the publicly available details on accreditation of the accredited CAB, except in the case of legal requirements, or when it obtains written release from the accredited CAB to disclose the necessary concrete information, which is otherwise of a confidential nature.

# **11 CHANGES WITH REGARD TO PREVIOUS REVISION**

In 2.2.1, the obligations of SA regarding exchange of information with other organizations due to changed requirements of IAF MD 23:2023 have been supplemented.

The requirements of IAF MD 7:2023 dictating action of national accreditation bodies in the case of perceived fraudulent conduct of CABs have been implemented at different spots herein. In 2.3, the obligation of CABs to act in the case of perceived data concealment or falsification or other fraudulent conduct in the field of the accredited activity has been added. In 5.7.1.2, it has been added that SA



or a verifier who has been convicted of a criminal offence or found liable for committing an offence related to the scope of accredited activities, or it has been found to deliberately furnish false information or conceal information.

In P3.5, requirements have been added for management system certification bodies` accreditation for the certification scheme of quality systems to SIST EN 15224: 2017 – Health care services – Quality management systems – Requirements based on EN ISO 9001:2015.

In P3.9, among additional requirements for the scheme for environmental verifiers, Commission Decision No. 2013/131/EU has been replaced by Commission Decision (EU) 2023/2463. Some minor text corrections and amendments have been made, which are marked in the text.

# 12 TRANSITORY AND FINAL PROVISIONS

# 12.1 Application of the provisions of the General Administrative Procedures Act

Regarding the method for calculating time limits as laid down in these Rules of accreditation, the provisions of the General Administrative Procedures Act shall apply, except where a different method of calculating time limits is specified herein.

# 12.2 Serving

The decisions by SA relating to the validity of accreditation as well as notifications of assessments and all types of contracts shall be served to the client by registered mail with return receipt. Should the client not accept such writing or not collect it at the post office, it is considered to be served on the 15th day after the writing was submitted to the post office.

Other writings determined to be served to the client, shall be sent by ordinary mail or e-mailed to the email address provided to SA by the client.

Normal notifications shall be served by e-mail to the e-mail address provided to SA by the client.

# 12.3 Limitations of accredited activities

Providing opinions and interpretations is not included in the scope of accredited activities of testing and calibration laboratories.

Accreditation of environmental verifiers for procedures performed outside the Community shall not be performed, as Slovenia has not adopted the decision on registration of organisations located outside the Community.

# 12.4 Transitional periods for implementation of new or amended requirements for competence of CABs

Transitional period for the implementation of ISO 22003-1:2022 at all levels of use shall be 3 years from the issue of the standard, i.e. until 30 June 2025. Certification bodies for food safety management systems according to ISO 22000 shall start using the new edition of ISO 22003-1:2022 in all initial audits by 30 June 2024 at the latest, or after obtaining accreditation for the issue of ISO 22003-1:2022,



whichever is later, and other holders of certificates by 31 December 2024 at the latest. By 30 June 2025, all certification bodies shall implement all the requirements of the standard that affect existing clients.

# **13 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.

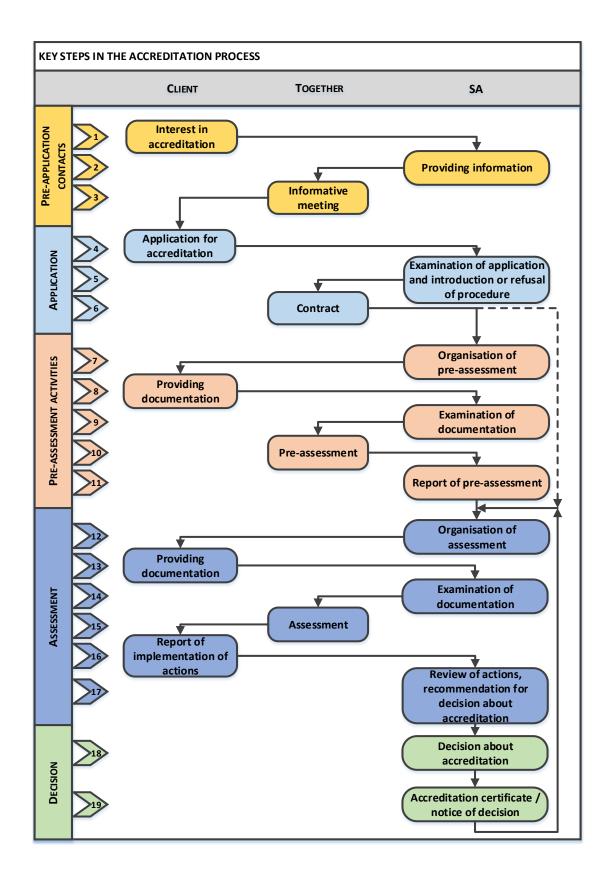
Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

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 or on SA's website.



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# ANNEX 1: ACCREDITATION PROCEDURE FLOWCHART





S03

# **ANNEX 2: ACCREDITATION FIELDS OF ACTIVITY**

Level in MLA structure		Standards, activities and explanations	
1.	Requirements for accreditation bodies	SIST EN ISO/IEC 17011, Regulation (EC) 765/2008, supplementary requirements, defined in EA mandatory documents and in IAF and/or ILAC documents, endorsed by EA as mandatory, as indicated in EA-INF/01	
2.	Conformity assessment activities	<ul> <li>a) Calibration</li> <li>b) Testing (including medical examinations)</li> <li>c) Inspection</li> <li>d) Certification of products, processes and services</li> <li>e) Management system certification</li> <li>f) Certification of persons</li> <li>g) Validation and Verification</li> </ul>	
3.	Harmonized Standards containing general requirements for conformity assessment bodies	<ul> <li>a) Calibration laboratories SIST EN ISO/IEC 17025</li> <li>b) Testing laboratories (b)1: SIST EN ISO/IEC 17025 Medical laboratories (b)2: SIST EN ISO 15189</li> <li>c) Inspection bodies SIST EN ISO/IEC 17020</li> <li>d) Certification bodies for products, processes and services SIST EN ISO/IEC 17065</li> <li>e) Management system certification bodies SIST EN ISO/IEC 17021-1</li> <li>f) Certification bodies for persons SIST EN ISO/IEC 17024</li> <li>g) Validation/verification bodies SIST EN ISO/IEC 17029</li> </ul>	
4.	Documents containing criteria supplementary to those contained in Level 3 documents	Sector-specific standards or other normative documents supplementing those in Level 3, e.g., ISO 22003-1 (e), ISO/IEC 27006 (e), Regulation (EU) 2018/848 (organic production and processing) (d), or sectoral schemes, e.g., Implementing Regulation (EU) 2018/2067 (g).	
5.	Scope of accreditation	Standards or other normative documents used by the accredited CAB to deliver an accredited conformity assessment activity (and which represent elements of scope of accredited activity in a detailed description of the scope), e.g., laboratory's testing method, SIST EN ISO 9001 or SIST EN ISO 14001 for management system certification body, product specifications, standards, regulations.	





# ANNEX 3: REQUIREMENTS FOR COMPETENCES OF DIFFERENT TYPES OF CONFORMITY ASSESSMENT BODIES

# P3.1 Calibration laboratories

#### General requirements:

Standard SIST EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017).

# P3.2 Testing laboratories

#### General requirements:

Standard SIST EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017).

#### P3.3 Medical laboratories

#### General requirements:

Standard SIST EN ISO 15189:2013, Medical laboratories - Requirements for quality and competence (ISO 15189:2012).

#### P3.4 Certification bodies for products, processes and services

#### General requirements:

Standard SIST EN ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012).

#### Additional requirements for schemes:

Sustainable forest management certification against PEFC Slovenian forest certification scheme: *PEFC SLO 05:2012, edition 1-8-2014, Certification and accreditation procedures for certification bodies carrying out certification,* 

PEFC SLO 06:2012, edition 1-8-2014, Requirements for auditors.

Certification of traceability of the origin of wood and other forest products against PEFC ST 2002: *PEFC SLO 05:2012, edition 1-8-2014, Certification and accreditation procedures for certification bodies carrying out certification,* 

PEFC ST 2003:2020, edition 14-2-2020, Requirements for Certification Bodies operating Certification against the PEFC International Chain of Custody Standard,

PEFC SLO 06:2012, edition 1-8-2014, Requirements for auditors,

PEFC ST 2001:2020, edition 14-2-2020, PEFC Trademarks Rules - Requirements.

Certification of organic production and processing in EU:

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, with amendments accessible on: <u>http://eur-lex.europa.eu/eli/reg/2018/848</u>, consolidated text,

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on



animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation) with amendments accessible on: <a href="http://eur-lex.europa.eu/eli/reg/2017/625">http://eur-lex.europa.eu/eli/reg/2017/625</a>, consolidated text,

RS OG No. 105/2022 – Regulation on organic production and processing of agricultural products and foodstuffs (No. 2608) and Rules on records in the field of organic production and processing of agricultural products and foodstuffs (No. 2612), in cases where the certification body performs its activity in Slovenia; where certification body performs its activity in other EU and EEC countries, the requirements laid down in the national legislations of those countries shall be taken into account as additional requirements for this scheme.

Certification of organic production and processing in third countries:

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 with amendments accessible on: <u>http://eur-lex.europa.eu/eli/reg/2018/848</u>, consolidated text,

Commission Delegated Regulation (EU) 2021/1698 of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies, with amendments accessible on: <u>https://eur-lex.europa.eu/eli/reg\_del/2021/1698</u>, consolidated text.

National legislation on organic production and processing of agricultural products and/or foods of third countries.

Certification of Trust Service Providers for electronic transactions for the purpose of Regulation (EU) No 910/2014, Article 20.1 / eIDAS):

ETSI EN 319 403-1, V2.3.1 (2020-06), Electronic Signatures and Infrastructures (ESI); Trust Service Provider Conformity Assessment; Part 1: Requirements for conformity assessment bodies assessing Trust Service Providers.

Additional requirements for notification purposes:

Construction products according to systems 1+, 1 and 2+:

Regulation (EU) no 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, with amendments accessible on: <u>http://eur-lex.europa.eu/eli/reg/2011/305</u>.

Non-harmonised construction products: Construction Products Act (ZGPro-1, RS OG No. 82/13).



Lifts and safety components for lifts (Module G):

Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts.

Non-automatic weighing instruments (Modules B, D, D1, G):

Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

Measuring instruments (Modules A2, B, C2, D, D1, E, E1, G, H1):

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

Radio equipment (Module B):

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

Personal protective equipment (Modules B, C2, D):

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

#### P3.5 Certification bodies for management systems

General requirements:

Standard SIST EN ISO/IEC 17021-1:2015, Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements (ISO/IEC 17021-1:2015).

#### Additional requirements for schemes:

Certification of food safety management systems according to ISO 22000:

Standard ISO 22003-1:2022 Food safety– Part 1: Requirements for bodies providing audit and certification of food safety management systems.

Certification of environmental management systems according to ISO 14001:

Standard SIST EN ISO/IEC 17021-2:2019, Conformity assessment – Requirements for bodies providing audit and certification of management systems - Part 2: Competence requirements for auditing and certification of environmental management systems (ISO/IEC 17021-2:2016).

Certification of quality management systems according to ISO 9001:

Standard SIST EN ISO/IEC 17021-3:2019, Conformity assessment – Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems (ISO/IEC 17021-3:2017).

Certification of energy management systems according to ISO 50001:

Standard ISO 50003:2021, Energy management systems – Requirements for bodies providing audit and certification of energy management systems.



Certification of occupational health and safety management systems according to ISO 45001:

Standard SIST-TS ISO/IEC TS 17021-10:2018, Conformity assessment – Requirements for bodies providing audit and certification of management systems - Part 10: Competence requirements for auditing and certification of occupational health and safety management systems.

Certification of quality systems according to SIST EN 15224:

Standard SIST EN ISO/IEC 17021-3:2019, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems (ISO/IEC 17021-3:2017).

Certification of quality management systems according to End-of-Waste criteria:

Council Regulation (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council,

Commission Regulation (EU) No 715/2013 of 25 July 2013 establishing criteria determining when copper scrap ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council,

Commission Regulation (EU) No 1179/2012 of 10 December 2012 establishing criteria determining when glass cullet ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council.

Additional requirements for notification purposes:

#### Measuring instruments (Module H):

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

Radio equipment (Module H):

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

#### P3.6 Certification bodies for persons

#### General requirements:

Standard SIST EN ISO/IEC 17024:2012, Conformity assessment - General requirements for bodies operating certification of persons (ISO/IEC 17024:2012).

#### P3.7 Inspection bodies

#### General requirements:

Standard SIST EN ISO/IEC 17020:2012, Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012).

#### Additional requirements for notification purposes:

Transportable pressure equipment:



# Directive 2010/35/EU of the European parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC, in connection to article I.1 of Annex I in Directive 2008/68/EC of the European parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods.

#### Final inspection of elevators:

Guidelines for the designation and notification of conformity assessment bodies based on the Act on Technical Requirements for Products and Conformity Assessment (ZTZPUS-1) and the Elevator Safety Regulation (Directive 2014/33/EU), March 2021.

#### Non-automatic weighing instruments (Modules F, F1):

Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

#### Measuring instruments (Modules F, F1):

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

#### P3.8 Validation and verification bodies

#### General requirements:

Standard SIST EN ISO/IEC 17029:2019, Conformity Assessment – General principles and requirements for validation and verification bodies (ISO/IEC 17029:2019).

#### Additional requirements for schemes:

Verifiers on greenhouse gas emission reports:

Standard SIST EN ISO 14065:2022, General principles and requirements for bodies validating and verifying environmental information (ISO 14065:2020),

Standard SIST EN ISO 14064-3:2019, Greenhouse gases – Part 3: Specification with guidance for the verification and validation of greenhouse gas statements (ISO 14064-3:2019),

Standard ISO 14066:2011, Greenhouse gases – Competence requirements for greenhouse gas validation teams and verification teams,

Commission implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council, with amendments available at <u>http://eur-lex.europa.eu/eli/reg\_impl/2018/2067</u>,

Commission implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012, with amendments available at <u>http://eur-lex.europa.eu/eli/reg\_impl/2018/2066</u>,

Commission delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Unionwide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council.



#### P3.9 Environmental verifiers

#### General requirements:

Standard SIST EN ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements (ISO/IEC 17021-1:2015).

Regulation (EC) No. 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No. 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC, with amendments accessible on: <u>http://eur-lex.europa.eu/eli/reg/2009/1221</u>.

#### Additional requirements for the scheme:

Commission Decision (EU) 2023/2463 of 3 November 2023 on the publication of the user's guide setting out the steps needed to participate in the EU eco-management and audit scheme (EMAS) pursuant to Regulation (EC) No 1221/2009 of the European Parliament and of the Council.

Standard SIST EN ISO/IEC 17021-2:2019, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 2: Competence requirements for auditing and certification of environmental management systems (ISO/IEC 17021-2:2016).