



S14

SCOPE OF ACCREDITATION

Table of contents

1	PURPOSE AND GENERAL PROVISIONS	2
2	TECHNICAL FIELDS	2
3	PRESENTING THE SCOPE IN THE ANNEX TO ACCREDITATION CERTIFICATE	2
4	TYPES OF ACCREDITED ACTIVITY SCOPES	3
4.1	Fixed scope	3
4.2	Flexible scope.....	4
5	CHANGES WITH REGARD TO PREVIOUS REVISION	7
6	TRANSITORY AND FINAL PROVISIONS.....	7
7	CONTROL OF THE DOCUMENT	7

1 PURPOSE AND GENERAL PROVISIONS

The decision on accreditation of a conformity assessment body (CAB) refers to its specific activities as defined in the Annex to Accreditation Certificate. This document lays down the rules for defining the scope of activity of an accredited CAB.

It is intended for the accredited CABs to adequately determine the scope in their applications to obtain or extend accreditation; the assessors in accreditation procedure to determine the appropriateness of the given scope; and to help the users of the accredited CABs' services in understanding and identifying the meaning of individual data provided in Annexes to Accreditation Certificates.

This document includes additional rules on accreditation procedure and additional requirements for accreditation in the case of flexible scope by complying to the principles and requirements of European Co-operation for Accreditation (EA), as set out in EA-2/15.

The document provides general requirements and rules applicable to all fields of accreditation, while specific and more concrete provisions as to the way of defining the scope in individual fields are specified in annexes hereto (S14dx).

This document and its annexes are 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 TECHNICAL FIELDS

The activities comprised within the scope of accreditation for individual fields of accreditation (i.e., testing, calibration, inspection, certification, validation and verification) are divided into the respective technical fields. These fields are used to provide an abridged description of the accredited activity and to classify the elements in individual Annex to Accreditation Certificate as well as to determine the activities of Slovenian Accreditation in general, as compiled in the document D05-11. Technical fields can be divided into sub-fields, or they can also be defined according to several categories of data ("multidimensional").

3 PRESENTING THE SCOPE IN THE ANNEX TO ACCREDITATION CERTIFICATE

In the Annex to Accreditation Certificate, the information on accredited activity shall be presented at two levels: first as a brief description of the activity using the technical fields as mentioned above, followed by all the details needed for the determination of the scope and its limitations.

A brief description of the activity, in which the fields and sub-fields, when required, are listed to which the accreditation of an accredited CAB refers, shall only provide initial information on the accredited activity and shall not define its scope.

Elements of activity for which a CAB holds accreditation, shall be precisely and unambiguously determined in a detailed scope of accreditation. The data defining individual element shall be as precise and clear as possible, including any specific characteristics, limitations and the like.

The way of presenting and the types of data to be indicated in order to determine individual element of the activity, are typical for individual fields of accreditation, and are described in annexes hereto.

In most fields of accreditation, reference to normative documents shall also be used to determine the type and scope of activity. When the activity is not (fully) determined by such publicly accessible documents, the CAB's internal documents may also be used for determination.

Normative documents for the needs of standardisation and accreditation include: international and national standards; laws and regulations; documents defining conformity assessment, which are issued by competent public law bodies or professional associations (proceedings of methods, instructions, technical specifications, technical approvals, technical guidelines ...); documents defining private certification schemes, and the like.

The CAB shall monitor changes to normative documents and introduce them into CAB's work in a timely manner. It shall take account of transitional periods, when defined for the use of the document referred to, and plan timely introduction of the change, including the procedure of extending the scope of accreditation in the case of fixed scope (see next chapter).

In the case of general legal instruments, their entry into force and entry into use thereof are always defined, and the CAB shall adjust its operation to the new rules within a time limit laid down in the general legal instruments.

As for other normative documents, SA shall consider the generally reasonable period for introduction of changes to be maximum 2 years after their generation, provided that there are no other requirements. A CAB which continues to use a cancelled document after that period, shall have reasonable grounds for such use (e.g., that the use of the cancelled standard is required by a general legal instrument; or that this is required by the client to meet specific and valid needs). When such cancelled normative document is used for defining the scope of accreditation, the inscription "cancelled" shall be added, except when the document is used in the context of a conformity assessment scheme that defines the use of a specific version (e.g., in accreditation for the purpose of notification). At each such use of cancelled normative documents, the CAB shall pay particular attention when making arrangements with its clients, who need to be informed to that effect.

4 TYPES OF ACCREDITED ACTIVITY SCOPES

We distinguish between a fixed type and flexible types of scopes. Flexibility of scope means SA-recognised competence of an accredited CAB to independently modify or supplement its accredited activity.

The way of presenting the data on particular scopes of accredited activities shall provide clear distinction between different types of scope and different aspects or levels of flexibility. The scope of accredited activity of a CAB may include parts of the fixed type and parts with different types or levels of flexibility.

4.1 Fixed scope

Fixed scope determines those accredited activities that were introduced in the CAB and assessed in the procedure of acquiring (and maintaining) accreditation. For changing the scope of accredited activity, the rules for extending accreditation shall apply. The types of data and the way of defining individual fields are specified in the annexes hereto.

4.2 Flexible scope

Determining the scope in this way means that the CAB may modify or extend the accredited activity within the framework stated in the description of flexibility of scope, without previously notifying SA. However, it shall in no case be allowed for modifications to refer to introducing another technical field of accreditation or including additional sites or organizational units at which the accredited activities had previously not been performed.

The parts of the scope of the accredited activity having the status of flexibility shall be specially indicated in the annexes to accreditation certificates, and also the way of presenting the scope shall be adapted accordingly. The flexibility shall be described through appropriate notes in such a way as to make clear which are its limitations.

A scope of accredited activity defined as flexible enables the accredited CAB to adapt faster to the needs of the users of its services, while at the same time, the CAB shall assume additional responsibility in ensuring the reliability of the results of conformity assessment and the compliance of all the procedures it uses in performing the accredited activity.

4.2.1 Rules of accreditation in the case of flexible scope

As a rule, a CAB which already holds accreditation for the technical field in question, and which has demonstrated adequate performance of its management system, can apply for a flexible scope, except in the case when the review of the application reveals that – due to specific circumstances – the fixed scope of accreditation is not suitable for the activity to be accredited.

Flexible scopes shall only be used in the fields for which specific rules are defined in annexes hereto.

When reviewing applications for a flexible type of scope and planning the necessary assessment activities, SA shall consider in addition to the general risks related to the accreditation procedure and its performance, also the risks related to the following aspects:

- The types or aspects of flexibility applied for (according to any flexibilities of scope already granted);
- The complexity of conformity assessment activities and SA's familiarity with these activities;
- The performance and stability of CAB's management system, the stability of CAB's technical staff responsible for controlling the flexible scope and the related activities;
- In CABs with already granted flexible scope: preliminary findings regarding the robustness of the CAB's process for controlling the flexible scope (including the extent of controls);
- Expectations of interested parties, including the legislator (see D02-05 in the case of need for developing a new type or area of flexibility).

Based on the findings of previous assessments (should they identify major deficiencies in the performance of the management system or provision of the necessary expertise and/or competence), or special risks related to individual types of activities, SA will advise the accredited CAB against application, or refuse an application already filed.

When applying, the CAB shall propose the way of presenting the scope for accreditation, by following as closely as possible the established way of presenting the fixed scope, and at the same time defining the flexible elements. Through the different stages of examining the application, assessing and reviewing prior to making a decision as to grant accreditation, the way of presenting the scope may be modified, when

necessary, in order to make the description unambiguous and credible. In addition, the ways of presenting by the CABs carrying out the same or similar activities with similar type of flexibility, should be made mutually consistent. In the case of flexible scope, the Annex to Accreditation Certificate shall contain reference to the list of accredited activities containing actual data on the scope of accredited activity, which shall be maintained by the accredited CAB.

In its assessments SA shall assess the CAB's competence to implement modifications, and the adequateness of all other elements of the management system, which support the process of developing or implementing modifications (e.g. policy and objectives, sharing of responsibilities, competencies of personnel, procurement reviewing process and cooperating with the customers, planning, validation/verification processes, risk control processes, etc.). Assessment of the performance of these elements of the management system shall normally be carried out also by checking recent cases of activity modifications. In doing so, the relevant requirements of the corresponding standard containing the requirements for competence, and additional requirements specified in this document and annexes hereto shall be considered.

Assessment reports shall present findings regarding the control of flexibility, while recommendations shall clearly refer to the grant or maintenance of appropriate type and level of flexibility.

Risks related to the flexibility of scope shall be considered when planning and carrying out assessments. In the case of introducing more complex modifications, and in the fields of activity with high risk, this may necessitate assessment of control of flexibility for individual types of activity at each regular surveillance.

To a CAB who is found not to control the flexibility of the scope (e.g. recurring unsuccessful introduction of modifications, and in particular, issue of reports/certificates with undue reference to accreditation), or who has not introduced any modifications in the activity with flexible scope for a longer period of time (two or more than two surveillance periods), or because of decreased trust in the competence of the accredited CAB to independently change or modify the accredited activity, SA may reclassify the scope to a fixed type, or change the level of flexibility. Therefore, the flexible way of presenting the scope only makes sense for CABs needing it because of the nature of their activity, and who make use of it in a proper way.

4.2.2 Additional requirements for accreditation

An accredited CAB shall have a documented process for developing and introducing new or modified activities, such that ensures successful control of modifications, and includes:

- Definition of requirements for development of activities;
- Consideration of flexibility limits;
- Implementation of the conformity assessment activity development procedure (including personnel training and implementation of all adaptations or modifications of the management system);
- Validation/verification of a new/changed activity;
- Responsibilities regarding control of flexible scope for individual parts of the activity;
- Verification and notification of customer in the process of reviewing procurements/contracts to the effect that the requirements expressed are within the defined limits of flexibility;
- Provision of unambiguous information on the scope of accredited activity.

Since in flexible scopes not all the data related to the accredited activity are specified in the Annex to Accreditation Certificate, it is the accredited CAB's duty to control these data and to inform the users and other interested parties about the actual state of scope. It shall maintain a list of accredited activities, which shall be accessible to the public and refer to the Annex to Accreditation Certificate. The accredited CAB shall specify the way and place of updating the list. The list shall contain at least the same detailed information on individual activity as in the case of flexible type of scope. The structure and elements of the list should follow as much as possible the methods SA uses for presenting fixed scopes in the given field of accreditation. The accredited CAB shall be responsible for the contents of the list of accredited activities to be aligned with the contents of the valid Annex to Accreditation Certificate (even in the event of suspension of scope of accreditation).

A new or modified activity cannot be added to the list of accredited activities before the development/implementation process has been concluded and approved. The accredited CAB may not make reference to its accreditation in relation with the new activity until this has been added to and published in the list of accredited activities.

A CAB who has obtained a flexible scope of accreditation shall explain to the customers the limitations to the flexibility of scope of its accredited activity and to make use of the specified options of modifying its activities. It shall ensure regular monitoring of the modifications and novelties in its activities, address the expressed and consider any anticipated needs of its users within the scope of its capacities, and plan any necessary modifications to the accredited activity.

The accredited CAB shall define the rules for addressing demands to carry out conformity assessment activities, which it has not introduced yet, but which are within the flexibility limits of its scope; these rules shall include:

- Notifying the customer to the effect that the implementation and issue of a report making reference to accreditation will only be possible once the new activity has been successfully introduced, and drawing his attention to the consequences (e.g. regarding time of implementation, rates, ...);
- Checking the availability of all the resources needed to conclude the introduction of the envisaged modification (also, whether all the sites presumably included in the performance of the activity are already indicated in the scope of accreditation or in the Annex to Accreditation Certificate);
- Successfully concluding validation/verification and the introduction process, approving the introduction and adding the new activity to the list of accredited activities.

Should the development/implementation of a modification turn out to be unsuccessful, the accredited CAB shall analyse the causes and effects and take the appropriate action. When necessary, this action shall include:

- Notifying the customers to the effect that, for the time being, issuing of a report with reference to accreditation will not be possible, and explaining the reasons;
- Revising the procedures and methods, should the cause be of technical nature and relate to a specific field of activity;
- When doubt is raised as to the competence for introducing modifications, also notifying SA in order to determine whether a change of the type of scope or a re-definition of the limitations of flexibility would be necessary.

5 CHANGES WITH REGARD TO PREVIOUS REVISION

The content of the document has been harmonized with the changes of EA-2/15 M: 2023. The title of Clause 4 has been supplemented. In 4.2.1, the list of risks to be considered when reviewing an application for flexible scope of accredited activity has been updated. In 4.2.2, the requirements for the process of developing and introducing new/changed activities of CAB have been supplemented. Some other minor changes have been made which are marked in the document.

6 TRANSITORY AND FINAL PROVISIONS

Transitory provisions for individual fields of accreditation are laid down in the respective annexes.

7 CONTROL OF THE DOCUMENT

The document is adopted by the SA Board after its content has been considered and adopted by the Accreditation Committee. If the SA Board disagrees with the proposal which was approved by the Accreditation Committee, it shall be referred back to the Accreditation Committee for consideration. Changes that do not affect the content can be adopted by the SA Board without the involvement of the Accreditation Committee.

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.