SLOVENSKA AKREDITACIJA

S14d2

S14 – ANNEX 2:

SCOPE OF ACCREDITATION IN CERTIFICATION BODIES, ENVIRONMENTAL VERIFIERS AND VALIDATION/VERIFICATION BODIES

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1 PURPOSE AND GENERAL PROVISIONS

The document provides specific and more concrete provisions as to the way of defining the scope in certification bodies, environmental verifiers and validation/verification bodies. General requirements and references are provided in general document S14.

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 TECHNICAL FIELDS

Certification bodies are distinguished by the type of conformity assessment they perform and by the conformity assessment standard inherent to the type of certification body. This document includes certification bodies for management systems (SIST EN ISO/IEC 17021-1), certification bodies for persons (SIST EN ISO/IEC 17024) and certification bodies for products/processes/services (SIST EN ISO/IEC 17065). Validation/verification bodies shall meet the requirements of SIST EN ISO/IEC 17029, and environmental verifiers the requirements of Regulation (EC) No 1221/2009 and SIST EN/ISO IEC 17021-1.

In certification bodies and validation/verification bodies, the technical fields are defined by the object of conformity assessment and, where reasonable, by the conformity assessment system (the rules, procedures, modules, AVCP system …).

The object of conformity assessment by certification bodies normally represents the type of management system, the group of products, processes, services or the category of personnel. In certification bodies for products, processes and services, individual groups of objects can relate to different certification systems.

The object of conformity assessment by validation/verification bodies is the claim (information declared by the client, which is the object of validation/verification). Validation and verification is always performed in conjunction with the validation/verification programme.

The technical fields in which the accreditation procedures have already been introduced are defined in the document D05-11.

Examples of definitions of a certification system are given in SIST EN ISO/IEC 17067.

For GHG reports verification bodies, the technical fields are defined in compliance with the Regulation (EU) No 2018/2067.

For environmental verifiers (Regulation (EU) No 1221/2009), the technical fields are defined by the NACE Code (Regulation (EC) No 1893/2006).

For food safety management systems, the technical fields are defined in ISO 22003-1 and for quality management systems in the field of medical devices according to ISO 13485, in IAF MD9.

A certification body, an environmental verifier and a validation/verification body, respectively, applying to obtain or extend accreditation shall use the classification laid down in the document D05-11 to specify its fields of activity. Should the activities for which it seeks to obtain or extend accreditation not have been

included in the classification, it shall specify the fields in its application as it deems appropriate, while the final specification will be made in accreditation procedure and added to the classification.

3 PRESENTING THE SCOPE IN ANNEX TO ACCREDITATION CERTIFICATE

In the Annex to Accreditation Certificate of a certification body, an environmental verifier and a validation/verification body, the information on the accredited activity is first provided in the form of a brief description of the object of certification/validation/verification and – where possible – the certification system, followed by all the details needed to define the scope and its restrictions.

The brief description of the activity shall only serve as first information on the accredited activity without defining its scope.

The detailed description of scope shall provide all the key elements, such as address of the site/s where the activities take place, additional requirements for competence (sector-specific standard/s) and the identification of the certification scheme and validation/verification programme, where relevant.

In general, the elements of detailed scope of accreditation in the Annex to Accreditation Certificate of a certification body, an environmental verifier or a validation/verification body are: the object of certification/validation/verification to which the scheme/programme refers; the defined certification system (modules, Assessment and Verification of Constancy of Performance (AVCP) System) and, where relevant, the designation of the normative document in which the requirements for acceptability of the system, product, process, service, personnel category or claim are described. The precise designation of the normative document shall be given, and when necessary, the restriction to individual parts of the document, which describe the acceptability requirements. In the case that the certification body or validation/verification body does not hold accreditation for all the fields stated in this document, this shall be specially indicated. The scope of accreditation of management system certification bodies is defined by technical fields.

For certification bodies which are accredited for notification purposes, the scope of accreditation is defined in a separate table so as to provide, to the greatest extent possible, the information needed for entry into the base of notified bodies (the key information includes: product/intended use/product range, procedure/module and identification of Annex, and/or Articles of the relevant Directive/Regulation). For certification bodies notified for the purpose of CPR (Regulation (EU) No. 305/2011), the key elements of detailed scope of accreditation are: European Commission decision; group of products/intended use; defined AVCP system; and harmonised standard and/or specification.

4 PRESENTING THE SCOPE OF THE FIXED TYPE

Beside the designation of the normative document, also the year or some other designation of the issue (version) with the corresponding amendments (usually defined as A, …) shall be indicated. In addition to the designation of the normative document, also its title is usually indicated in the scope.

The introduction of any modified versions shall normally be assessed in the course of ordinary surveillance visits. The certification body/environmental verifier/validation/verification body shall not obtain the right to make reference to accreditation for a new version of normative document until the change has been made in the relevant Annex to Accreditation Certificate.

5 PRESENTING THE SCOPE OF THE FLEXIBLE TYPE

Flexible-type scopes are used in the fields of certification of products/processes/services and persons. Flexibility of scope is not possible with certification bodies accredited for notification purposes for CPR (Regulation (EU) No. 305/2011). Nor is the flexibility of scope used in the fields of certification of management systems, GHG reports verifiers and environmental verifiers.

Such way of defining the scope means that the certification body may, without prior notification of SA, implement minor modifications to the certification schemes, such as:

- introducing adjustments of documents issued on the basis of a normative document (e.g. supplements/amendments to the normative documents, amendments of regulations), in the fields of certification in which these documents are frequently issued. In this case, the normative document shall be indicated in the scope of accreditation together with the year of issue, while supplements/amendments to the normative document need not be indicated. Major modifications (new editions of normative documents) must be notified by the certification body to SA and will be considered in accordance with the relevant procedures for modifications, in the same way as in the case of fixed scope;
- introducing modifications due to new editions of normative documents, when such modifications do not change the conformity assessment procedures or methods. In the scope of accreditation, the normative documents shall be indicated without the year. For specific fields of its activities (normative documents), the CAB shall define the types of modifications it may introduce by itself in the context of its flexibility. However, major modifications of a normative document must be notified by the certification body to SA and will be considered in accordance with the relevant procedures for modifications, in the same way as in the case of fixed scope;
- extending the use to additional products in the G group in the field of organic production and processing of agricultural products and foodstuffs;
- extending the use to additional agricultural products and foodstuffs within individual product category, for which there exists an approved specification for protected agricultural products and foodstuffs.

Not all of the information defining the accredited scope (e.g. information on applicable amendments or supplements to the normative document, year of issue of the normative document, specification) need to be indicated in the Annex to Accreditation Certificate for a flexible scope. Only the normative document shall be indicated under the description of the certification scheme with or without the year of issue, or just the certification system, meaning that the certification body is competent to implement extensions and modifications of its activities in this context.

All information that can be modified shall be published by the certification body in a list of accredited activities, which by its structure and elements of contents shall be the same as the one used by SA for presenting fixed scopes in a given certification field. The general additional rules for accreditation procedure and additional requirements for accreditation in the case of flexible scope are defined in the document S14 and shall also apply, *mutatis mutandis,* to certification bodies.

A flexible scope shall be defined in the Annex to Accreditation Certificate so that the fields and limitations of flexibility are clearly shown. For example, in:

- Header of the table: *Type of Scope: Flexible (possibility of introducing minor modifications to the scheme)*

  and Note below the table:

  When necessary, the certification body may introduce minor modifications to the scheme (e.g. introduction of newly issued annexes or supplements to normative document). Data on the current status of the scope are maintained and published by the certification body on its website.

  or

  When necessary, the certification body may introduce minor modifications to the scheme (e.g. adaptation to new revisions of normative document). Data on the current status of the scope are maintained and published by the certification body on its website.

  or

  When necessary, the certification body may introduce minor changes to the scheme (e.g. extension of use to additional products in G group). Data on the current status of the scope are maintained and published by the certification body on its website.

  or

  When necessary, the certification body may add, within individual product category, agricultural products and foodstuffs for which there exists an approved specification. Data on the current status of the scope are maintained and published by the certification body on its website.

  and in the end note to the Annex:

  A list of accredited activities with relevant data on the activities from the flexible part of the scope is published by the certification body on the website: state the link.

6 CHANGES WITH REGARD TO PREVIOUS REVISION

In Clause 5, the possible flexibility types in introducing minor changes of certification schemes have been updated and the flexibility for introducing additional schemes within the framework of certification system has been withdrawn.

7 TRANSITORY AND FINAL PROVISIONS

N/A

8 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 copy of this document shall be located in i4 (SA's 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 hereof 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.