

**National Accreditation
Agency of Ukraine**

Approved by
the NAAU Decree
№172-Я dated 05.09.2014

MANAGEMENT SYSTEM

Instruction

“On drawing up the scope of accreditation of a testing laboratory”

Instruction “On drawing up the scope of accreditation of a testing laboratory”			NAAU
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page 1
			Total number of pages 6

I. General provisions

This instruction is elaborated with a view of ensuring the appropriate quality of works related to drawing up the scope of accreditation on the part of conformity assessment bodies (hereinafter – CABs), namely laboratories, during preparation of a set of documents for submitting an application for accreditation, and also on the part of accreditation assessors and experts in the course of documents’ analysis, on-site assessment and in the process of drawing up of documents after on-site assessment.

While developing this Instruction, the requirements of EA-4/18, ILAC-G18:04/2010 have been considered as requirements of EA-2/15:2008 concerning introduction of generalized scope of accreditation.

In most cases, CABs should form the accreditation scope by means of listing the title of the object (products, materials, substances, etc.), giving for each position title of testing and (or) characteristics (parameters) to be determined and opposite each - identification of normative documents for testing methods.

In some cases, where it possible and appropriate CABs can form the generalized scope of accreditation a part of accreditation scope (or even all accreditation scope).

For formation the generalized accreditation scope the laboratories should outline the positions that correspond to a generalized testing methods (directions, disciplines and sub-disciplines on testing methods) and according to them to develop the draft of part of accreditation scope in generalized view and a strategy of participation in programs of interlaboratory comparisons. The foundation of the scope of accreditation shall be such layout and such sequence of positions so as to provide for the clearly outlined directions, disciplines and sub-disciplines in such generalized view as far as possible and logical. Testing laboratories should take into account when the project of generalized scope is submitted they must have evidence of sustainable experience of carrying out testing for each position for all types of testing and objects that were generalized, and to provide these evidences when analyzing documentation, accreditation and monitoring. In all cases, the laboratory must keep a list of all current methods covered by the accreditation, for accreditation body’s review. In addition, the Passport of CAB should contain enough information confirming the justification of the formation of accreditation scope in generalized view. Generalized scope can be granted only when CAB has demonstrated that it has a process of design / development, which it can use for additional conformity assessment or for extension to additional scopes covered by the generalized scope, but not received before.

Note. CABs should understand that not for all testing methods and types of testing is possible presentation of accreditation scope as generalized. Formation of accreditation scope as generalized accreditation scope is rather an exception than the rule.

II. Order of actions

For laboratories

1. A CAB before submitting an application for accreditation shall analyze objects of (products, materials, substances, etc.), and set of testing and (or)

Instruction “On drawing up the scope of accreditation of a testing laboratory”			NAAU	
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page	2
			Total number of pages	6

characteristics (parameters) to be determined and which it is going to reflect in a draft scope of accreditation, taking into account requirements of EA-4/18, ILAC-G18:04/2010.

If case of adoption decision to form part of the accreditation scope as a generalized scope of accreditation the CAB as a result of analysis shall outline directions, disciplines and sub-disciplines in compliance with the profile and type of its activity. The level and depth of detailing of the structure of its work a laboratory shall further use for rubricating and structuring of a draft scope of accreditation. According to the outlined directions, disciplines and sub-disciplines a laboratory builds its strategy of the quality assurance of testing results, in particular, the participation in interlaboratory comparisons' programs.

2. While drawing up a draft scope of accreditation (F-08-01.17) a CAB shall take into account data of self-assessment of the testing methods (F-08-01.33). Information on testing methods shall be placed by a CAB in accordance with a form 2.2 of TL's Passport (F-08.01.19) and a draft scope of accreditation. A CAB includes to the scope of accreditation exclusively those methods with respect to which the data on sustainable experience is available and the results on self-assessment of the testing methods are completed in a form of reports.

3. CAB forms the accreditation scope as a list of titles of the object (products, materials, substances, etc.) for each of them provides appropriate list the title of testing and (or) characteristics (parameters) and also identification of normative documents for testing methods.

When forming accreditation scope in the generalized view a CAB in a draft scope of accreditation shall stipulate a name of the direction, following a discipline and sub-discipline, and further a list of methods for each sub-discipline.

4. When forming accreditation scope in the generalized view in the cell "Name of an object (product, material, substance etc.)" a CAB shall stipulate in a maximum possible for it general manner the data on the objects of testing for each method against which the testing of these objects is carried out. The detailed data on all possible objects of testing shall in any event be given in a form 2.1 CAB's Passport.

5. For each separate testing method a separate line in a table shall be used.

6. If a separate testing method is given in several standards, a CAB shall stipulate each standard in a separate line of a table after providing title of testing and (or) characteristics (parameters) to be determined.

7. The information about testing method shall be stipulated with necessary and appropriate detailing (e.g., standard, clause).

8. Information on standards shall be cited with indicating of the year. For other normative documents all necessary bibliographic data shall be given. If a method is taken from the books, collections, magazines and other sources, a full bibliographic description of the source shall be provided. In the absence of identification of a testing method (e.g., number), a source page shall be provided.

9. If testing are performed against requirements of the work instruction, a CAB shall be firstly obliged to provide an appropriate method-source (standard), on the

Instruction "On drawing up the scope of accreditation of a testing laboratory"			NAAU
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page 3
			Total number of pages 6

basis of which it has been developed, and afterwards, if so desired by a laboratory, it shall indicate a designation of the work instruction.

10. Names of tests/indicators in a draft scope of accreditation, in a form 2.2 of a Passport, form on data shall comply with a name in standards (or other normative documentation). Names in standards and other normative documentation are primary.

11. Other data on testing methods and title of testing and (or) characteristics (parameters) to be determined, a laboratory shall keep in the completed and updated form in the relevant internal documentation on a permanent basis other information on methods and indicators, not contained in a draft of accreditation scope (limitation of methods, measurement ranges, uncertainties and other data).

12. In case of availability in the CAB's structure the remote divisions located in another territory and have another addresses, the accreditation scope is formed by parts with indicating the titles of all remote divisions with a list of appropriate titles of the object (products, materials, substances, etc.) , titles of testing and (or) characteristics (parameters) to be determined and identification of normative documents and testing methods.

13. A CAB stipulates "List of persons authorized to endorse the testing minutes" at the very end following a main table.

For assessors and experts on accreditation

1. Assessors/experts on accreditation during analyzing of documentation and on-site assessment shall verify the correctness of identifications of normative documents and testing methods, title of testing and (or) characteristics (parameters) to be determined and title of the object (products, materials, substances, etc.).

2. In the case of CAB's submission of generalized accreditation scope, auditors/experts on accreditation shall verify the correctness of the drawing up of the scope in accordance with the outlined directions, disciplines and sub-disciplines as well as the correctness of the headings.

3. Auditors/experts on accreditation shall verify the compliance of testing methods in a draft scope of accreditation of a CAB with data on self-evaluation of testing methods and information on methods of a form 2.2 of a TL's Passport (F-08.01.19). Testing methods, with respect to which the data on sustainable development is absent and the results of self-evaluation of testing methods are not completed in the form of reports, shall be withdrawn from a draft scope of accreditation of a CAB.

For responsible executor

Drawing up of the scope of accreditation is conducted in accordance with a form "Scope of accreditation" (F-08.01.17), while taking notice of instructions provided in Remarks to a form.

Chief Specialist of the Division
on Laboratories' Accreditation

Ihor Gogoman

Instruction "On drawing up the scope of accreditation of a testing laboratory"			NAAU	
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page	4
			Total number of pages	6

Appendix 1 (informative)

Illustration of a scope of the accreditation of a testing laboratory for food products and agricultural raw materials

Number i/s	Name of the object (product, material, substance etc.)	Name of testing and (or) properties (indicators, parameters) to be determined	Name of normative documents and testing methods
1	grain crops	1. Physical and chemical testing	
		Determination of moisture	ГОСТ 13586.5-93 ДСТУ ISO 6540:2007
		Determination of moisture	ГОСТ 10847-74, ГОСТ 28418-89 (ISO 2171-80)
		1.1 Testing by method of atomic absorption spectrometry	
		Determination of the mass fraction of toxic elements (lead, cadmium, copper, zinc)	ГОСТ 30178-96
		1.2 Chromatographic testing	
		1.2.1 Gas and thin layer chromatography	
		Determination of organochlorine pesticide residues (α -ГХЦГ, β -ГХЦГ, γ -ГХЦГ, heptachlor, aldrin, ДДД, ДДЕ, ДДТ)	МУ 2142-80 ДСТУ EN 12393-1:2003 ДСТУ EN 12393-2:2003 ДСТУ EN 12393-3:2003 ДСТУ ISO 14181:2003
2	Meat fresh and frozen, food offal products, meat and food offal products, domestic poultry fresh and frozen, rabbits meat and game	1. Physical and chemical testing	
		Determination of mass fraction of fat	ГОСТ 23042-86
		Determination of protein	ГОСТ 25011-81
		1.1 Testing by method of atomic absorption spectrometry	
		Determination of the mass fraction of toxic elements (lead, cadmium, copper, zinc)	ГОСТ 30178-96
		1.2 Chromatographic testing	

Instruction "On drawing up the scope of accreditation of a testing laboratory"			NAAU	
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page	5
			Total number of pages	6

		1.2.1 Gas and thin layer chromatography	
		Determination of organochlorine pesticide residues (α -ГХЦГ, β -ГХЦГ, γ -ГХЦГ, heptachlor, aldrin, ДДД, ДДЕ, ДДТ)	MB 2142-80 ДСТУ EN 12393-1:2003 ДСТУ EN 12393-2:2003 ДСТУ EN 12393-3:2003 ДСТУ EN 1528-1:2002

Illustration of a generalized scope of the accreditation of a testing laboratory for food products and agricultural raw materials

Number i/s	Name of the object (product, material, substance etc.)	Name of testing and (or) properties (indicators, parameters) to be determined	Name of normative documents and testing methods
		1. Physical and chemical testing	
		1.1. Chromatographic testing	
		1.1.1. Gas chromatography	
1	Food products, agricultural raw materials	Mass fraction of pesticides	ДСТУ EN 1528-1-2002 ДСТУ EN 12393-1:2003 ДСТУ EN 12393-2:2003 ДСТУ EN 12393-3:2003
		1.1.2. Liquid chromatography	
2	Food products	Mass fraction of sweeteners	ДСТУ EN 12856:2003
		1.2. Atomic absorption spectrometry testing	
3	Food products, agricultural raw materials	Mass fraction of toxic elements	ГОСТ 30178-96
		2. Molecular genetic testing	
4	Food products, agricultural raw materials	Qualitative and quantitative detection of GMOs by real time PCR	ДСТУ ISO 21569:2008 ДСТУ ISO 21570:2008 ДСТУ ISO 21571:2008 ISO 21569:2005 ISO 21570:2005 ISO 21571:2005

Instruction “On drawing up the scope of accreditation of a testing laboratory”			NAAU	
Revision 04 dated 05.09.2014	Developed by: Gogoman I.	Checked by: Busol O.	Page	6
			Total number of pages	6