Management of application scope and accreditation scope

Implemented by: Director of testing, calibration and medical laboratories, Director of certification and inspection bodies, assessment team, file managers, technical committee.

Responsible for implementation: Director of testing, calibration and medical laboratories/ Director of certification and inspection bodies

Controled by: Director of Accreditation Department
Ardita MELE

Approved by: General Director
Pranvera FAGU

1. Purpose

This document provides the process for establishing the assessment scope and/or accredited scope after the assessment process.

2. Scope

This document applies to the management of the scope used for initial assessment, surveillance and/or reassessment.

3. Responsibilities

Responsibilities for implementation of this procedure has Director of testing, calibration and medical laboratories/ Director of certification and inspection bodies. This procedure has to be implemented by Director of testing, calibration and medical laboratories, Director of certification and inspection bodies, assessment team, file managers and technical committee.

4. Definitions

For the purposes of this document, the terms and definitions given in the ISO/IEC 17011:2017 standard and the abbreviations listed in the DPA Quality Manual annex have been used.

5. References

S SH ISO/IEC 17011:2017- Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
DA-PO-002 Accreditation policy"
DA-PO-015 "Policy for accreditation programme"

6. Procedure

6.1 The initial application scope or extension scope is provided by applicant through the application forms. For each type of conformity assessment activity, DPA has published the relevant application forms. It is the responsibility of Director of testing, calibration and medical laboratories/director of certification and inspection bodies and file manager to review the application scope according to resources review. It is the task of file manager to determine the suitability of application scope. In case of surveillance, the lead assessor prepares the assessment according to accreditation scope.

6.2 The file manager and Director of testing, calibration and medical laboratories/director of certification and inspection bodies define the assessment team based on application scope, database of competence (DA-DT-001) and annex of DA-FO-045.

6.3 Based on risk associated with activities, locations and personnel covered by the application scope/accreditation scope, the assessment team assess the performance of a sample of conformity assessment activities representative of the scope of application/scope of

accreditation. The assessment team includes all the selected activities, locations and personnel to the assessment plan according to the form DA-FO-002. In case of testing, medical and calibration laboratories the activities which are planned to be witnessed or vertical audited during the assessment are referred with the number according to form DA-FO-022. In case of management system certification, in generally, the activities which are planned to be witnessing or vertical audited during the assessment are referred according to relevant classification (EA codes, classification according to standards or guidelines). During one accreditation cycle, the assessment team assesses the conformity assessment activities representative of the scope of accreditation at relevant locations.

6.4 Each technical assessor performs witnessing /vertical audit during the assessment and reports according to relevant forms. Technical assessor provides to the assessment report all the information on witnessing and/or vertical audits, which were not performed and reason for that.

6.5 In case of initial assessment or extension the accreditation scope is proposed and signed by the assessment team as an accompany document of its proposal on accreditation.

6.6 Director of testing, calibration and medical laboratories/director of certification and inspection bodies/chairman of relevant technical committee and lead assessor signed the accreditation scope as an accompany document of recommendation for accreditation to General Director. The accreditation scope signed by decision makers is traceable with the accreditation scope signed by assessment team.

6.7 The decision on accreditation is accompany with accreditation scope signed by general director. The accreditation certificate is valid only with reference to accreditation scope.

6.8 Based on the accreditation scope the assessment team compiles the assessment programme for all accreditation cycle**.**

7. Expression of application scope and accreditation scope

In the application form and accreditation scope of testing/calibration laboratories the information for the scope shall be organised like in the table above.

Tab. 1 Description of list of analysis in the application form of testing/calibration laboratories

No.	Material / Product / Matrix, to test	Test Name / property measured	areas of measurement and / or Test (1)	Test techniques	Standard and/or Test methods	Observation	Opinion & Interpretation	Standard / Method for sampling (5)	Location Code °(6)
1	Naphta	Determ	0,710-0,740		STASH				1

		ination of density in 20 oC -15 oC	gr/cm3 ± 0.001 gr/cm3		33-86				
2	Textile	Determination of mass	0-200g		ISO 9073-1:1989				0

(1) Show scope of application of analyses (eg. 0 ÷ 350 KN; 0,5 ÷ 12%; 1 ÷ 300 mg/Kg) or limit of determination (eg. >0,1 mg/Kg; >10 UFC/g).
(2) Show only for tests chemical, technique of used test. (eg. Gas chromatography, testing)
(3) Indicate standard, method, method of laboratory.
Note: The standard and/or method is admitted to be the last issue. In case the lab. uses an older version it must notify this to the list. All abbreviation of standards or methods must be explained at the end of the list eg (ISO- International Organisation for standardization, EN- European Standard, ASTM - American Society for Testing and Materials, (SMEDP) -Standard Methods for the Examination of Dairy Products AOAC
(4) Indicate for each test if you ask to be accredited for opinions and interpretations.
(5) Indicate standard/method of sampling (only for tests that laboratory carries out itself sampling)
(6) *Location*: When DPA accredits the capacity for a laboratory to perform test out of its premises this is indicated in the scope in a specific column as for instance "Location Code" Laboratory or on site or as an alternative "Category" 0 for in laboratory, 1 for on site, 2 for both

In case of medical laboratories, the application form and accreditation scope will be presented as in the table above

N °	Material / Product / Matrix, to test	Test name/ measured property	Areas of measurement and / or Test	Test technique	Standard / test methods	Notes, changes,observations	Opinion and interpretation	Sampling Standard / sampling methods
1								
2								
3								

The accreditation scope for quality and environmental management system certification bodies shall be formulated according to IAF ID 1.
The expression of accreditation scope for quality managemetn system for medical devices certification bodies shall be based on IAF MD 8.
The expression of accreditation scope for food safety management system certification bodies shall be done with categories and subcategories according to ISO/TS 22003 standard.
The expression of accreditation scope for energy management system certifcation bodies shall be done with category defined in ISO 50003 standard.

The expression of accreditation scope for business continuity management system certification bodies shall be done with groups according to DPA guideline DA-IN-006.
The expression of accreditation scope for certification bodies which will be accredited according to certification schemes ISO 27001, ISO 20000-1, ISO 37001, ISO 39001, will make reference to relevant standard.
The expression of accreditation scope for certification bodies which will be accredited according to certification schemes ISO 27001, except the relevant standard, DPA will include the phrasing "all IAF codes".

The expression of application scope for inspection bodies shall be according to the above table:

No	Material or system that will be inspected	Type of inspection (e.g: periocial, initial, etc)	Standard or method of inspection	Frequency of inspction in one year	Location

The expression of accreditaiton scope for inspection bodies shall be according to the above table:

No	Material or system that will be inspected	Type of inspection (e.g: periocial, initial, etc)	Standard or method of inspection

The scope of accreditation for persons certification bodies shall include the information about the persons or group of persons, certification scheme and title of certification scheme. The application scope and accreditation scope shall be according to the above table:

No	Persons or group of persns	Standard or other normativ document	Title of standard or normativ document

The scope of accreditation for products, services and processes shall contain the following information:

Products, services or process to be certified

Specification for the product, service or process – document(s) that contains the requirements for conformity of the products, services or processes
Certification procedure – document that describes the methods/procedures for certification.

To describe and structure the accreditation scope DPA complements the accreditation scope with the indication of IAF ID 1 accreditation codes

Expression of accreditation scope for GLOBALG.A.P. v 6.0

EAC 1 Products from Agriculture, Forestry and Fishing

Product/Service/Process	Certification criteria	Certification procedure
Integrated Farm Assurance - Plants	GLOBALG.A.P. General Regulations V6 Smart and/or GFS Principles and Criteria IFA v6 Smart for fruit and vegetables Principles and Criteria IFA v6 Smart for flowers and ornamentals Principles and Criteria IFA v6 GFS for fruit and vegetables	GLOBALG.A.P. General Regulations V6 Smart and/or GFS Principles and Criteria IFA v6 Smart for fruit and vegetables Principles and Criteria IFA v6 Smart for flowers and ornamentals Principles and Criteria IFA v6 GFS for fruit and vegetables CAB certification procedure
Chain of Custody	GLOBALG.A.P. General Regulations V6 Smart and/or GFS CoC Principles and criteria	GLOBALG.A.P. General Regulations V6 Smart and/or GFS CoC Principles and criteria CAB certification procedure

If application for accreditation only includes option 1, this shall be described in the scope. IF it includes option 2 nothing is referred, as it is implied that both options are included.
The scope may refer to territorial limitations

7. History

Date of review	Number of review	Prepared by	Description of changes
20.05.2010	0	Ermira FYSHKU	First version

12.01.2015	1	Vilma Mara	There have been changes to the document head o page about numbers telephone and email address In page 2 is amended number of Law
21.02.2022	2	Ardita Mele	Annex 1 is deleted
08.06.2022	3	Ardita Mele	The reference to ILAC G28:07/2018 for formulating the field for inspection bodies has been removed
04.01.2024	4	Suela Kromidha	Expression of the accreditation program for medical laboratories based on EA 4/17:2022
14.11.2024	5	Ardita Mele	Change of reference and addition in paragraph 7 for the management of the accreditation program for product certification bodies.