

SUN PROTECTION FIELD - INTERLABORATORY COMPARISON

*Compliance control of inter-laboratory comparison following
ISO 17043 principles*

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Agenda

Summary	1
Steps	2
General control	3
Technical control	4

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Summary

Beyond the certification of the competence of laboratories assessment of sun protection, it is important to have confidence in the conformity of equipment, consumables and services provided by suppliers with standards and methods.

For this, each product (equipment and consumable) or service (calibration and interlaboratory campaign) shall meet a complete technical specification extracted from the standards and methods.

INTERLABORATORY COMPARISON	
Type:	Sun Protection field - Interlaboratory comparison
Goal(s) and scope(s):	Check the quality and technical specifications of interlaboratory comparison provider to comply with sunscreen testing methods
Reference(s):	ISO 17043

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Steps

General control

To ensure a minimum quality level, the company should have a quality system management (not even in the specific field).

At least one Certification / Label is required.

Note: If none is available, a complementary audit should be necessary including management system, subcontracting services, control of records in general and technical, internal audits, management reviews, equipment, accommodation and environment, confidentiality, etc.

Technical control

The second part concerns the technical characteristics inspection of the competence of providers of Proficiency Testing Schemes (PTS) and for the development and operation of PTS dedicated to the sun protection field.

Note: If the company is already ISO 17043 accredited but not for sunscreen testing campaigns, therefore, further control should be performed only for Interlaboratory Comparisons - Sunscreen and none documents requested for Interlaboratory Comparisons - General.

Note: If the company is already ISO 17043 accredited for the sunscreen testing campaigns, therefore, no further control should be performed any parts.

General control

Subject	Yes	No	NA /NE	Comment
1. GENERAL				
1.1. <i>Certification / Label</i>				Certificate to be provided
➤ ISO 9001				
➤ ISO 13485				
➤ ISO 17025				
➤ ISO 17043				
➤ FDA registered				
➤ GMP (Good Manufacturing Practice)				
➤ GLP (Good Laboratory Practice)				
➤ GCP (Good Clinical Practice)				

Technical control

Subject	Yes	No	NA /NE	Comment
2. INTERLABORATORY COMPARISONS – General				
<i>2.1. Personnel</i>				
❖ Provide evidence of qualifications, training program or of recognition by professional or regulatory bodies				
<ul style="list-style-type: none"> ➤ Persons who issue proficiency testing scheme have to demonstrate a knowledge of: <ul style="list-style-type: none"> • Standards or specifications for which PTS is dedicated • Facility's management system and quality control data • Design and planning PTS • Particular types of sampling including determination of stability and homogeneity of proficiency test item • Prepare, handle and distribute proficiency test items • Conduct statistical analysis and give opinions and interpretations • Authorize the issue of proficiency testing reports 				
<i>2.2. Design and preparation of PTS</i>				
❖ Provide documents presenting design (road map) and preparation of PTS				
<ul style="list-style-type: none"> ➤ Plan with decisions of objectives, purpose and basic design including at least the following main parts: <ul style="list-style-type: none"> • Name and activities of different actors involved (proficiency testing provider, subcontractor (if applicable), advisory group) • Range values and/or characteristics of interest to test in the PTS round • Information to supply to participants and the time schedule (frequency/dates and the deadlines for the return of results) • Detailed instructions on methods/standards/procedures to use by participants for performing the test • Description of the statistical analysis to be used • Criteria for the evaluation of performance of participants • Technical meetings with participants to include technical difficulties or remarks raised in previous round 				
<ul style="list-style-type: none"> ➤ Implement procedures to ensure: <ul style="list-style-type: none"> • PTS are prepared in accordance with the plan • Appropriate acquisition, collection, preparation, handling and storage • Criteria for suitable homogeneity and stability respect and assessment in final form • Packaging, labelling and distribution of proficiency test items 				

Subject	Yes	No	NA /NE	Comment
3. INTERLABORATORY COMPARISONS – Sunscreen				
3.1. <i>Data analysis</i>				
❖ Provide documents presenting statistical part				
➤ Statistical design to consider the accuracy with uncertainty required or expected for each measurand in the proficiency testing				
➤ Data analysis methods to be used to identify the assigned value and evaluate participant results with: <ul style="list-style-type: none"> • Check the validity of data entry, data transfer, statistical analysis and reporting • Summary statistics and performance statistics explained • The influence of outliers on summary statistics estimation 				
3.2. <i>Instructions for participants</i>				
❖ Provide instruction for participants				
➤ Instruction about proficiency test round process <ul style="list-style-type: none"> • Prior notice before sending items • Documented instructions during proficiency test round and any appropriate instructions on handling items • Specific and detailed instructions on the manner of recording and reporting test or measurement results 				
3.3. <i>Report</i>				
❖ Provide a sample report				
➤ Several information to include (not limited to): <ul style="list-style-type: none"> • Name and contact details of different actors (proficiency testing provider and coordinator) including person(s) authorizing the report • Description of the proficiency test items • Status of report (draft, final...) • Include data covering results of all participants • Statistical analysis explanation 				