

SUN PROTECTION FIELD: SPECTRORADIOMETRIC CALIBRATION

*Compliance control of spectroradiometric calibration following
COLIPA - Guidelines for monitoring UV radiation sources – Edition 2007*

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Technical control	Erreur ! Signet non défini.
Conclusion	Erreur ! Signet non défini.

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) and service (calibration and interlaboratory campaign) shall meet a complete technical specification extracted from the standards and methods including a mandatory annual documentary inspection.

SPECTRORADIOMETRIC CALIBRATION	
Type:	Sun protection field – Spectroradiometric calibration
Goal(s) and scope(s):	Check the quality and technical specifications of spectroradiometric calibration to comply with in vitro and in vivo sunscreen testing methods
Reference(s):	COLIPA – Guidelines for monitoring UV radiation sources – Edition 2007

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Steps

General control

To ensure a minimum quality level, the inspected company should have a quality system management.

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 spectroradiometric calibration dedicated to the sun protection field.

Note: If the company is already ISO 17025 accredited for calibration and testing in spectroradiometric field, therefore, further control will be performed only for Spectroradiometric Calibration - Sunscreen and none documents will be requested for Spectroradiometric Calibration - General.

General control

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

Technical control

Subject	Limit	Yes	No	NA /NE	Comment
2. SPECTRORADIOMETRIC					
<i>2.1. General</i>					
➤ Qualified expert	External testing laboratories/experts capable to perform the UV-source measurement and provide a certificate should be accredited by an accreditation institution				
➤ Condition	The instruments must have been adapted to room temperature with record at least once before and after the measurements.				
➤ Position	The instruments has to lie exactly in the same plane as the irradiated skin/plate surface and at the same distance from the source. The spectroradiometer should be set up on a vibration-free place with constant room temperature and as far as possible from powerful sources of magnetic fields.				
➤ Warm-up	Warm-up times of the lamps (including shutters in the open position to allow radiation going through the optical filters), pre-cooling times for photo-detectors (when necessary), etc. must be followed in order to conduct measurement at the operating temperature. The spectroradiometer should be warmed up for at least 30 minutes too.				
➤ Other radiation	When it is not possible to exclude other radiation expect from the source from the entrance optics of the spectroradiometer, a measurement of the background radiation is recommended.				
➤ Several light guides equipment	Each light-guide / spot has to be measured individually with at least 3 measurements				
➤ Broad-beam UV-sources	Spectra from different locations under the beam should be recorded				
➤ Irradiance measurement	Beside UV radiation, the total irradiance of an UV source may include visible light (VIS, 400-800 nm) and infrared light (IR-A, 780-1400 nm) and can be measured with a spectroradiometer or a thermopile.				
➤ Radiometer calibration	When available, absolute radiometer calibration has to be performed during the spectroradiometer calibration by using the same UV source in the same position as the spectroradiometer and a correction factor shall be determined.				
<i>2.2. Technical</i>					
➤ Minimal spectral range	250 - 780 nm				
➤ f-number (focal distance divided by the limiting aperture)	About 4				
➤ Spectral FWHM Bandwidth	1.0 – 1.2 nm in the UV range, maximum 5 nm in the visible and IR-A ranges				
➤ Slit function	< 10-3 of maximum at 2.5 * bandwidth away from the centre (e.g. Hg spectral calibration lamp at 253.65 nm or a laser line, such as the 325 nm line of a He-Cd laser)				
➤ Stray radiation	< 10-6 (This criterion applies to sources used for SPF testing)				
➤ Wavelength repeatability	Better than ± 0.05 nm, in the UV range				
➤ Wavelength accuracy	Better than ± 0.1 nm in the dUVB and ± 0.2 nm for dUVANo specifications for the visible or IR-A ranges				

➤ Calibration in wavelength	A pen-type mercury lamp should be used to check accurate wavelength calibration and linearity before each use. Examples of usable wavelengths given for Hg, in air at 15°C/760mm Hg: 253.652, 275.278, 289.360, 296.728, 334.148, 404.656, 407.784, 435.833, 546.075, 576.961, and 579.067 nm; + possibly using the second order of diffraction: 507.304, 593.456 and 668.296 nm.				
➤ Input optics: integrating sphere or diffuser, fitted for UV	The area of the entrance port must be less than half of the exposed area where the irradiance at sample / skin level is measured. In addition, a centring mechanical adapter should enable the correct repositioning of the probe at the same exposed site				
➤ Spatial angular sensitivity	Should be close to a cosine response (i.e. cosine error smaller than $\pm 10\%$ for incident angles $< 60^\circ$)				
➤ Maximal spectral irradiance	$> 30 \text{ W.m}^{-2}.\text{nm}^{-1}$ at the maximum of the spectrum Attenuating filters / so-called neutral densities can be used, once their spectral transmission at the operating temperatures has been characterized.				
➤ Determination threshold (minimal irradiance to be measured)	$< 10^{-4} \text{ W.m}^{-2}.\text{nm}^{-1}$ at 290 nm				
➤ Detection threshold	$< 5.10^{-5} \text{ W.m}^{-2}.\text{nm}^{-1}$ (for SNR = 1 at 1 nm FWHM)				
➤ Integrating time	Should be adjustable in a 10-fold range of pulse length, i.e. at least 100 ms for each wavelength when measuring a flash-lamp operating at 50 Hz				
➤ Calibration in absolute irradiance	A certified calibration bulb is used for the instrument calibration. The spectral irradiance certificate of calibration bulb must be traceable to a national standard for spectral irradiance and be less than 1 year old or less than 50 hours used.				
➤ Step width in UV range	1 nm				
➤ Step width in VIS and IR-A ranges	5 nm maximum; interpolation to 1 nm authorized				
➤ Scan speed	< 3 minutes for the UV range				
➤ Samples per reading of the Analogous to Digital Converter	At least 5				
➤ Stability	Whenever the environment changes (temperature difference higher than 3 K, switch on or off of devices including magnetic parts electrically activated, air Relative Humidity change $> 10\%$), at least the wavelength calibration and preferably the absolute irradiance calibration too should be checked on site. Temperature stabilization of the spectroradiometer and automatic, periodic (at least hourly) zeroing of the dark current are recommended.				