Pathway to Developing a UV-C Standard – A Guide to International Standards Development

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What is an international standard?

Given the broad impact of standards on product functionality, trade and market access, there has been some discussion about the definition of "international standards." This discussion sometimes colloquially is referred to as the "I" vs. "i" debate. While some choose to define international standards as only those standards developed by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) or the International Telecommunications Union's Standardization Sector (ITU-T), others have taken the view that the procedures followed during the development of a standard define whether the standard is an international standard.

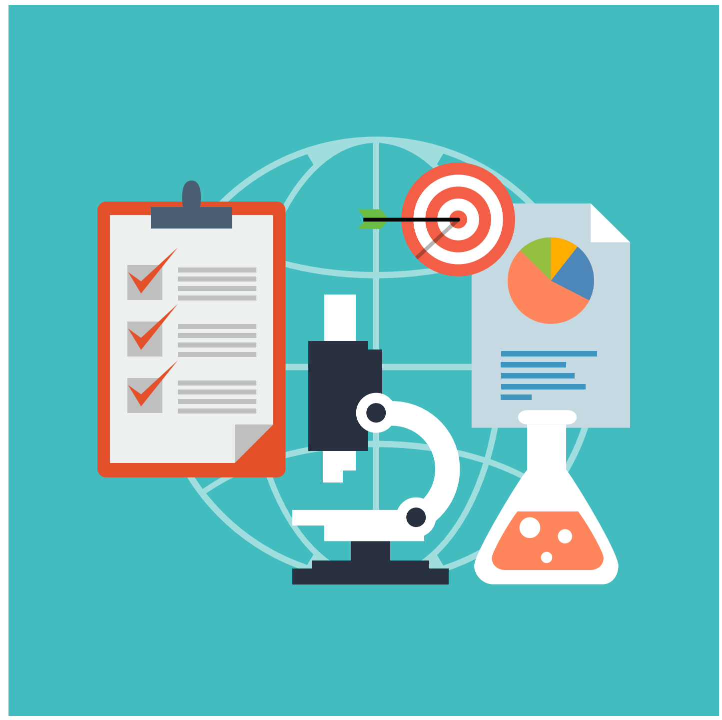
Definition according to the World Trade Organization

This discussion has assumed significance due to the emphasis placed on the use of international standards by the World Trade Organization's Agreement on Technical Barriers to Trade (WTO-TBT Agreement).[1] Specifically, clause 4 of Article 2 on the Preparation, Adoption and Application of Technical Regulations by Central Government Bodies notes that,

> *"Where technical regulations are required, and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as the basis for their technical regulations except where such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of legitimate objectives pursued …."*

This language clearly emphasizes the imperative to use international standards. Just as importantly, clause 2.5 notes that,

> *"Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably* ***presumed not to create an unnecessary obstacle*** *to international trade." (emphasis added)*



However, the agreement does not define what an international standard is.

Following significant debate and discussion among stakeholders about what standards are international standards, the TBT Committee during its second triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade in 2000, issued additional guidance that helps with the understanding of what are international standards. In section C.19 (G/TBT/9), the committee noted that a diversity of bodies was involved in the preparation of international standards and that different approaches and procedures were used by them in their standards development activities.

The committee adopted a set of principles – openness, impartiality, transparency, consensus, relevance, effectiveness, coherence and developing country interests, as principles that are important for international standards development. Standards that are developed using these principles are international standards in the US and in other jurisdictions around the world. In some jurisdictions, national legislation defines international standards as only those standards developed by ISO, IEC or ITU-T.

Standard-developing bodies

There are numerous standards-developing bodies around the world. Bodies such as ISO and IEC are private sector standards developing organizations that include representation from countries around the world. In ISO and IEC, country interests are represented by a National Standards Body that could be a private sector organization (e.g., ANSI for the US or DIN for Germany) or could be a governmental organization (e.g., BIS for India or KATS for the Republic of Korea). There are many other models of standards-developing bodies that develop international standards. Such organizations as ASTM International, ASME, IEEE, etc. facilitate standards development based on the representation of individual experts acting in their capacity as individuals or representing the interests of their organizations.

Still other organizations such as the World Wide Web Consortium (W3C) or the Internet Engineering Task Force (IETF) follow yet other models for developing consensus-based specifications in open and transparent processes. This diversity of approaches contributes to a rich tapestry of organizations that mostly complement each other and creates a vital ecosystem of standards-developing organizations that can meet the standardization needs in a timely and robust manner, resulting in fit for purpose standards.

Relationship with ANSI and international standards (American National Standards)

The American National Standards Institute (ANSI) is the National Standards Body for the US. ANSI is a private sector organization that acts as a federation representing the interests of US domiciled standards developing organizations, industry, government, academia and consumers in ISO, IEC and in regional standardization efforts such as those for the Americas (COPANT) or the Pacific Area Standards Congress (PASC). All US entities participating in any ISO or IEC standardization activity participate through an ANSI-accredited effort. This effort can reside within a US-domiciled standard developing organization or some other organization that can convene a range of interests relevant to that standards development effort. In some instances, US domiciled organizations choose to seek accreditation as Accredited Standards Developers (ASD).[2]

The process of accreditation requires the development of a documented process that is assessed by ANSI on a regular interval. In addition, there is a cost for maintaining the accredited status. Such as accreditation is an indication that the standards development process used by the SDO follows ANSI's requirements for openness, due process and consensus, which are elements of ANSI Essential Requirements. Often, ASDs will voluntarily chose a standard that they have developed designated as an American National Standard (ANS). This designation further conveys the robustness of the process by which the standard was developed. The designation conveys that the standards development process was open, balanced, consensus-based and transparent manner. Different organizations may choose to seek ASD designation or ANS designation for specific standards based on the value they see[3] in such designation for the standard or for the users of their standards. Currently, approximately 11,000 standards carry the ANS designation.

Standard-developing organizations associated with UV applications and general lighting in the US

The lighting industry has a history of more than 120 years. Due to this, several SDOs participate in standardization of the lighting industry. Among these SDOs are the Illuminating Engineering Society (IES), ASTM International and the National Electrical Manufacturers Association (NEMA).

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Each of these organizations have a sector of expertise that contributes to developing documentary standards including test methods, form factors, performance levels, nomenclature and definitions. Many times, these SDOs collaborate when topics cross boundaries. IUVA has worked with American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), particularly, ANSI/ASHRAE Standard 185.2-2014 – Method of Testing Ultraviolet Lamps for Use in HVAC&R Units of Air Ducts to Inactivate Microorganisms on Irradiated Surfaces."

The measurement and application of light has been the territory of the Illuminating Engineering Society (IES).[4] The IES produces several types of documents, including laboratory methods (LM), technical memorandums (TM), recommended practices (RP) and design guides (DG). The IES relies on technical committees made up of subject experts that range from lighting component and lighting system manufacturers, lighting designers, laboratory measurement experts, test equipment manufacturers and government representatives. Consensus is achieved through a rigorous process that includes experts who are IES members and non-IES members.

The Standards Committee has three groups: Lighting Science, Lighting Practice and Lighting Applications. The IES is an ANSI-accredited SDO and has developed many working relationships with other organizations including ASHRAE, NECA (National Electrical Contractors Association), NALMCO (interNational Association of Lighting Management Companies), ALA (American Lighting Association) and the IDA (International Dark Skies Association). The IES would be an appropriate partner for the development of UV-C light measurement procedures.

ASTM International,[5] which used to be the abbreviated form of the American Society for Testing and Materials, is a US-domiciled developer of international standards that has more than 12,000 standards. ASTM standards within the lighting industry mainly deal with the measuring the properties of components used in developing lighting products including chemical analysis, spectral reflectance, spectral transmittance, and weathering of materials. Lighting related standards in ASTM are developed in its technical committees such as E12 – Color and Appearance, C24.40 – Weathering, and E35.15 on Antimicrobial Agents. ASTM's documentary standards include guides, test methods and performance levels. Recently, the E35.15 has produced ASTM E3135-18 – Standard Practice for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation Against Microorganisms on Carriers with Simulated Soil. This test method provides a consistent approach to determining inactivation doses required. ASTM would be suitable partner for the development of UV-C required performance levels for the disinfection of surfaces.

> The UV-C disinfection community can leverage the standard developing infrastructure of the general lighting community to produce standards to ensure a reliable, consistent market.

NEMA[6] has created documentary standards that define a product, process or procedure with reference to one or more of the following: nomenclature, composition, construction, dimensions and operating characteristics or performance focusing on the form-factor and electrical requirements within the lighting industry. The Solid-State Lighting Product Group and the Lighting Systems Division have developed many of the standards that define the form-factor or specific dimensions for light bulbs, the electrical requirements of ballasts and the performance color characteristics of fluorescent lighting among other topics. A NEMA partnership would provide the opportunity to standardize components and electrical performance within UV-C technologies.

UV-C documentary standards

The UV-C disinfection community can leverage the standard developing infrastructure of the general lighting community to produce standards to ensure a reliable, consistent market. The first proposed standard is a test method for the measurement of radiant flux of low-pressure (LP) mercury tubes developed through an ANSI approved standards development process. This document has a scope describing the procedures to determine the total radiant flux (W) and/or the distribution of radiant intensity (W/sr) at a specific wavelength of 254 nm under standard electrical and operating conditions.

Most of this work would leverage the process written by Lawal, et al. – "Method for the Measurement of the Output of Monochromatic (254 nm) Low-Pressure UV Lamps" published in *IUVA News*.

Standard electrical and operating conditions include the tolerances on voltage waveforms, voltage regulation, ballast conditions, ambient temperature and allowable air flow. Additional conditions are controlled, including lamp orientation, seasoning, preburning and stabilization time in order to increase the reproducibility among laboratories. The calibration and measurement procedures are described for using an integrating sphere system, a goniometer system or using the Keitz formula. The difference between using a broadband measurement vs. a spectroradiometer system are presented. Additional guidance is provided, including measurement uncertainty considerations and information that should be provided in a test report.

The second proposed standard to develop is a test method for the measurement of radiant flux of medium pressure mercury tubes and xenon tubes. The document scope describes procedures to determine the total spectral radiant flux (W/nm) and/or the distribution of radiant intensity (W/sr) over a wavelength range of 200 to 400 nm under standard electrical and operating conditions. Many of the conditions and the guidance presented in the LP mercury tubes document would be similar. More emphasis would be placed on calibrating the spectroradiometer within the measurement system. In addition, a collaboration with NEMA may be required to establish standard ballast conditions for the operation of the tubes.

The third document is a test method for the measurement of radiant flux of LED packages. The document scope describes procedures to determine the total spectral radiant flux (W/nm) and/or the distribution of radiant intensity (W/sr) over a wavelength range of 200 to 400 nm under standard electrical and operating conditions. The electrical and thermal management of the LED in a standard condition is significantly different than mercury tubes. The IES has published a measurement method for LEDs identified as LM-85-14 – Approved Method: Electrical and Photometric Measurements of High-Power LEDs. While this document focuses on the 380 nm to 780 nm wavelength range, the protocol and techniques discussed in the standard can be extended to cover the 200 to 400 nm range.

The first three proposed standards have dealt with the measurements of components that are installed into fixtures. The next two documents would cover a test method for the measurement of radiant intensity distribution (W/sr) of a UV-C luminaire and a test method for the measurement of irradiance (W/m^2) of a UV-C luminaire at a specific distance. The data collected using these two methods would allow an application to be modeled.

While this is not a complete list of documentary standards for UV antimicrobial devices used to attack HAI and MDRO

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pathogens in healthcare facilities, which is mission of the Healthcare/UV Working Group formed by the IUVA, an additional proposed standard is the recommended practice for implementing surface UV-C disinfection. The recommended practice would provide guidelines on the required amount of UV-C light to accomplish inactivation of different pathogens. The practice also may describe modelling techniques such as establishing a scenario and then – by using ray tracing software, the data collected for the UV-C luminaire and UV-C reflectance data collected using ASTM standards – determine if the dose is large enough to accomplish the required task.

Advantages of documentary standards

There are several advantages to establishing documentary standards that cover test methods and performance level requirements. Sound technical standard measurements benefit the user and the manufacturer by eliminating discrepancies and misunderstandings. The user can select and obtain the proper product for the application based on consistent quantities. The manufacturer can establish warranties based on solid measurements ensuring reliability. This provides clarity, consistency and certainty in the product value chain.

By establishing a test method for the components used in a fixture (LP mercury tubes, MP mercury tubes, xenon tubes and LED) a fair comparison is possible between older technologies and newer technologies. If performance levels or dose of a wavelength required for inactivation is established, then the requirement is providing the number of photons needed independent of technology.

Documented standard test methods allows for the measurement infrastructure to develop. Third-party laboratories can invest in equipment and capabilities to support the disinfection industry. The laboratories then can become accredited, which means an accreditation body like the National Voluntary Laboratory Accreditation Program (NVLAP) or A2LA or ACLASS can assess the laboratory management and quality system against a well-established, and globally accepted, international standard, ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories.

Accreditation ensures that the laboratory has the competence to test a product to certain standards and has the appropriate quality management systems in place.

Once a measurement infrastructure is established for UV-C disinfection, if the need for regulation develops, voluntary documented standards offer a clear path forward, as the use of these standards for the technical regulations can obviate the need for additional burdensome requirements and meet existing global trade obligations. ■

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