

## ISO 9000 Certification and Your HunterLab Instrument Part I. Summary of ISO Requirements

“Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment,” International Standard ISO 10012-1:1992(E) contains guidelines for you as a user of measuring equipment that is used to demonstrate your product’s compliance with its specifications. This Applications Note provides a summary of these guidelines as they relate specifically to your HunterLab instrument. Requirements deserving elaboration will be handled in more detail in upcoming Applications Notes. In order to be consistent with the ISO publication, you and your company (the user of HunterLab equipment) will be referred to here as “the Supplier.”

*Note: This information is presented as a guide only. HunterLab makes no claims concerning your potential ISO 9000 certification and your requirements may differ slightly from those suggested here.*

The specific requirements are listed in Section 4 of the ISO document. Brief comments on each subsection are provided below.

**4.1, General:** Your implementation of the requirements listed in the rest of the ISO publication must be documented. This documentation would normally include procedures for use and maintenance of the instrument and records of the performance and service of the instrument. HunterLab provides the basis for this documentation in the form of its User’s Manuals, Service Manuals, and service records, but the Supplier is responsible for tailoring this general information to suit the particular application. Although HunterLab maintains service records on each instrument it manufactures, it is recommended that the Supplier maintain a complete copy of the instrument service record and other related documents for potential inspection by auditors.

**4.2, Measuring equipment:** a) The measuring equipment must meet or exceed the performance level required by the application. Performance parameters include accuracy, stability, range, resolution, and repeatability. For example, if your measurement method requires spectral data between 360 and 750 nm, the instrument you choose must be capable of measuring in this wavelength range. HunterLab product literature and User’s Manuals list the performance specifications for each instrument it manufactures. Suppliers generally use these specifications as criteria for proper performance. b) This required performance must be documented and maintained. You must perform diagnostics to ensure proper operation of the instrument and take corrective action if the instrument does not meet the desired level of performance. HunterLab

recommends performance diagnostics in instrument User's Manuals. Suppliers can also develop their own diagnostic testing procedures. c) Any conditions necessary for meeting the required level of performance must be maintained. For example, if the instrument meets its performance specification within a certain temperature range, the instrument must only be used in an area where that temperature range is maintained.

**4.3, Confirmation system:** a) You must have a system in place for the management, confirmation, and use of the measuring equipment and instrument standards. This is the responsibility of the Supplier, but guidance is given by HunterLab in its User's Manuals, Service Manuals, and other documentation such as this Applications Note. b) Each instrument shall have an authorized officer to ensure the operation of the unit. This officer would be appointed by the Supplier and be a member of the Supplier's staff. c) When the instrument or standards are replaced or recalibrated, ISO procedures must be followed. HunterLab is itself an ISO 9001-certified supplier, and so follows ISO-acceptable procedures in its manufacturing and servicing (including recalibration) processes. Also, certification that your ISO procedures may require, such as Certificates of Traceability (for standard tiles) and Certificates of Calibration (for instruments) are available from HunterLab.

**4.4, Periodic audit and review of the confirmation system:** Periodic internal audits must be performed by the Supplier and appropriate corrective action must be taken based on the findings of the audit.

**4.5, Planning:** The Supplier shall ensure that the instrument to be used can meet the required level of performance for the application before commencing use of the instrument for that particular application. Instrument performance specifications are available in HunterLab product literature and User's Manuals. Knowledge of the particular application and product to be measured is the responsibility of the Supplier.

**4.6, Uncertainty of measurement:** The Supplier must take into account any uncertainties associated with measurements. Uncertainties may be associated with the instrument performance, proper/improper use of the instrument, and the methodology employed for selection of samples and their measurement. Instrument performance can be gauged by examining the instrument specifications and most current diagnostic results. Assuring proper use of the instrument and an appropriate methodology for measurement are the responsibility of the Supplier, although guidelines are given in HunterLab User's Manuals and other publications such as this Applications Note.

**4.7, Documented confirmation procedures:** Procedures for performing measurements and instrument diagnostics must be documented and followed. Measurement procedures used may be published standard methods such as ASTM or TAPPI methods, HunterLab's written instructions (guidance provided in the User's Manual), or a method provided by the purchaser of the Supplier's products. For tracking the performance of the instrument, statistical process control is recommended.

**4.8, Records:** The Supplier shall keep records on each instrument it owns. This information should include the make, model, and serial number for each instrument and the serial number and established values for each of its standard tiles. Records should also include service records, certificates/records of calibration and traceability, expected instrument specifications, procedures and intervals for instrument confirmation, and environmental conditions required. HunterLab

maintains records of each instrument it manufactures, including make, model, serial number, standard information, and service records, but it is recommended that the Supplier maintain a complete copy of the instrument service record and other related documents for potential inspection by auditors. Instrument specifications and requirements for environmental conditions can be found in product literature and/or User's Manuals.

**4.9, Nonconforming measuring equipment:** Any instrument that is malfunctioning or does not meet required performance specifications must be taken out of service until the problem is corrected. HunterLab provides repair service for all its instruments until five years have elapsed since its last manufacture. If repairs are extensive or no longer available, the instrument may be scrapped.

**4.10, Confirmation labeling:** Instruments should be labeled or coded with an indication of performance status. If the instrument cannot be used for any reason (e.g., it does not pass its diagnostic tests), it must be clearly marked that it cannot be used. Labeling must also include when the instrument must next be tested or calibrated. Diagnostic procedures are outlined by HunterLab in its User's Manuals and a calibration interval is recommended, but implementation of this labeling is the responsibility of the Supplier.

**4.11, Intervals of confirmation:** Instruments and standards should be confirmed (tested/and or recalibrated) periodically. The period between confirmations should be established based on the stability and usage of the instrument. HunterLab can make recommendations on confirmation intervals, but the Supplier's individual needs will dictate the actual period chosen. HunterLab provides diagnostic and repair services, as well as instrument and tile recalibration. This topic will be covered in greater detail in a later Applications Note.

**4.12, Sealing for integrity:** Access to adjustable settings that affect instrument performance shall be sealed to prevent tampering. HunterLab instruments are generally manufactured in such a way as to make such adjustments accessible only to HunterLab service technicians, or under the guidance of a service technician, through removal of instrument covers or access to the back of the instrument with a special tool. If there is any reason to believe tampering is possible, it is the responsibility of the Supplier to label, cover, or otherwise inform users that tampering is unacceptable.

**4.13, Use of outside products and services:** The Supplier must ensure that products and services purchased meet required quality levels where they affect the quality of products to be sold to customers. Color measurement instruments are generally used for quality control of products, so this requirement definitely applies to instruments and other supplies purchased from HunterLab. HunterLab is itself ISO 9001-certified, so all instruments have been thoroughly tested under HunterLab's quality program. However, the Supplier may wish to run standard diagnostics on new or recently-serviced HunterLab instruments prior to use.

**4.14, Storage and handling:** A system for handling, transporting, and storing instruments must be in place. HunterLab User's Manuals provide information on appropriate operating and storage conditions for instruments (temperature, type of surface required, etc.). When instruments are transported, it is recommended that they be returned to the original factory packaging, or, if that packing material is unavailable, pack the instrument in a sturdy, well-sealed box with at least six inches of foam or other cushioning material surrounding all sides of the instrument. The instrument should not be allowed to directly contact any surfaces of the box.

Remove the sample clamp (if you have one) from the instrument port and tape the port opening. Be sure to ship at an insured rate.

**4.15, Traceability:** Instruments should be calibrated using standards that are traceable to national or international measurement standards. If such standards do not exist, suitable reference materials or industry standards are acceptable. Documentation of the chain of traceability is required. All HunterLab colorimeter standards are traceable to both U.S. National Institute of Standards and Technology (NIST) and National Physical Laboratory (NPL) of England standards. HunterLab spectrophotometer standards are in reference to the NIST perfect reflecting diffuser calibration. Gloss standards are also traceable to NIST standards (except for 75° TAPPI measurements, for which NIST does not maintain a standard). A Certificate of Traceability is shipped with each instrument that HunterLab manufactures and is updated each time standards are recalibrated. The uncertainty associated with calibrated values is also reported on each Certificate of Traceability. Replacement Certificates of Traceability are obtainable from the HunterLab Technical Services Department if required.

**4.16, Cumulative effect of uncertainties:** The cumulative effect of the uncertainties of each link in the chain of calibration should be taken into account. HunterLab provides a cumulative uncertainty value on the Certificate of Traceability for your reference. This must be taken into account in one of the following ways: a) If an absolute value standard must be met (e.g.,  $L^*$  must be  $50 \pm 1$  unit), the uncertainty associated with the instrument's measurement cannot be more than the allowable color variation (1 unit) OR b) The product specification can be based on a sample's *difference* from an ideal product standard. The uncertainty associated with a standard tile's calibrated values is in the absolute color (or gloss) values. If an instrument is in reasonable condition, difference measurements are generally accurate even if absolute color values are not correct.

**4.17, Environmental conditions:** The instrument must be restandardized as often as required by the environmental conditions. Temperature, humidity, particulates, electromagnetic interference, and other environmental changes can cause drift, which should be accounted for. Information concerning appropriate environmental conditions for use of HunterLab instruments is given in HunterLab User's Manuals.

**4.18, Personnel:** The Supplier must ensure that trained personnel operate the equipment in an appropriate manner. Personnel selection and training is the responsibility of the Supplier, although HunterLab does offer seminars and various types of on-site training, which may be personalized as needed. HunterLab User's Manuals are also helpful in training users.

**Reference:**

International Standard ISO 10012-1:1992(E), "Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment," *ISO 9000 International Standards for Quality Management*, 4th ed.

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