

## Applications Note

$\Delta = 2t + \frac{\lambda}{2}$  (must equal a whole number of  $\lambda$  for a bright fringe or

$$n\lambda = 2t + \frac{\lambda}{2}$$

$$t = \frac{n\lambda - \frac{\lambda}{2}}{2} = \frac{\lambda}{2} \left( n - \frac{1}{2} \right)$$

substituting

$$D^2 = 2r \left[ \frac{\lambda}{2} \left( n - \frac{1}{2} \right) \right]$$

AN 1085



## Summary of ISO 9001: 2015 Requirements

**... implementation of the requirements listed in ... the ISO publication must be documented.**

### Abstract

International Standard ANSI/ISO/ASQ Q9001-2015, "Quality management systems—Requirements," contains guidelines for you as an operator 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 and the records appropriate for documentation.

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 Organization.”

**Note:** *This information is presented as a guide only. HunterLab makes no claims concerning your potential ISO 9001 certification, and your requirements may differ slightly from those suggested here.*

Under ISO 9001: 2015’s “process-based” approach to quality management, instrumental measurement falls under the “Check” part of the “Plan-Do-Check-Act” (PDCA) methodology. Instrumental measurements allow you to monitor your product, comparing it against product requirements and any applicable regulatory requirements and documenting the results, as required by section 4.1(e) of the ISO document.

The specific requirements concerning measuring equipment are found in many different areas of the ISO document. Brief comments on each of these areas are provided below.

**4.2.1 General:** Your implementation of the requirements listed in the rest of the ISO publication must be documented. This documentation would normally 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 procedures for use and maintenance of the instrument and for 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 Organization is responsible for tailoring this general information to suit the particular application, or for obtaining appropriate published procedures like ASTM or TAPPI methods or a method provided by the purchaser of the Organization’s products. Although HunterLab maintains service records on each instrument it manufactures, it is recommended that the Organization maintain a complete copy of the instrument service records and other related documentation for potential inspection by auditors.

The types of documents and records appropriate for your HunterLab instrument are listed and discussed below.

- Instrument file, in which the make, model, serial number, location, etc. for each instrument and the serial number and established values for each of its standard tiles would be kept. The make, model, serial number, and standard tile values are provided by HunterLab with your instrument. Look for your tile data sheet (spectrophotometers), blue standards card (D25s), and certificate of traceability, which are provided in your standards case. A photocopy of the labels on the backs of your tiles also provides useful information.
- Standard operating procedures for using the instrument to make measurements and reporting results. These procedures should include information on how often and how to standardize the instrument, how to confirm that the instrument is operating properly, and how to perform normal measurements using the instrument. They may be composed by the Organization based on instructions given in the User’s Manuals or include a direct reference to a published procedure like an ASTM or TAPPI method or to a measurement method provided by the Organization’s customer. You may want to provide a fill-in data sheet with each procedure to ensure that the proper data is recorded.

**7.4.1 Purchasing process:** Before buying measuring equipment, the Organization must decide what is required of such equipment and must evaluate and record the results of the evaluations of the instruments that are being considered. Performance parameters for color measurement equipment typically 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 throughout this wavelength range. HunterLab product literature and User's Manuals list the performance specifications for the instruments it manufactures. Organizations generally use these specifications as criteria for proper performance.

**7.4.3 Verification of purchased product:** The required performance of the instrument (and software) purchased must be verified by the Organization. Some companies refer to this as the Operation Qualification, or OQ, process, by which you would perform diagnostics that verify the proper operation of the instrument and that it meets the requirements that were specified for the instrument before purchase. HunterLab recommends performance diagnostics in its User's Manuals. Organizations can also develop their own diagnostic testing procedures.

Standard operating procedures for testing and maintaining the instrument, which should be composed by the Organization based on instructions given in the User's Manuals. You may want to provide a fill-in data sheet or log with each procedure to ensure that the proper data is recorded.

These procedures should include information on how often and how to perform diagnostic tests on the instrument and what to do if the results are out of specification.

An example of a procedure you might implement for confirmation of the repeatability of a spectrophotometer is given below. Similar methods could be implemented for other types of instrument checks, standardization, and normal instrument operation.

#### **Repeatability Test Using Agera**

Once a week, at the beginning of Monday's day shift, perform the repeatability test as described below.

1. If the instrument was turned off over the weekend, turn the instrument on and allow it to warm it up. Meanwhile, clean the black glass and white tile and allow the tiles to return to room temperature. Note the date and time the tiles were cleaned on the Cleaning Log.
2. Insert the port plate and standardize the instrument with UV filter nominal.
3. Configure the Master Color Data display to show dE\* using D65/10°.
4. Center the instrument's white standard tile at the measurement port. Do not move or remove the tile for the remainder of the test.
5. Read the white tile as a standard.
6. Configure the timed read feature to automatically make 20 more measurements with a read interval of 7 seconds and then initiate reading of the tile as a sample.
7. When all measurements are complete, examine the dE\* values. If no value in the dE\* column is greater than **0.09**, record the largest dE\* value on the Repeatability Log and the test is complete. If any of the dE\* values is greater than 0.09, call the Shift Supervisor.

The Shift Supervisor would then also have a procedure to follow when the instrument fails the test, which might include such steps as a drift check and signal level check. If the instrument fails these tests too, the supervisor might then be required to stop using it and contact HunterLab regarding service. Note that the repeatability readings in this example were recorded in a log. Tracking of diagnostic data in logs, trend charts, or Statistical Process Control (SPC) systems is recommended and helps fulfill the records requirement of the next bullet.

Service records and the results of any diagnostic tests performed. Although HunterLab maintains service records on each instrument it manufactures, it is recommended that the Organization maintain a complete copy of the instrument service records for potential inspection by auditors.

#### **7.6 Control of monitoring and measuring devices:**

The instrument must be calibrated and verified periodically. This involves regular standardization and verification at the Organization's site, as well as calibration verification by a HunterLab service technician. To fulfill the first part of the requirement, HunterLab recommends standardizing its instruments at least every eight hours. Other diagnostic tests, such as reading the green tile and didymium filter should also be performed periodically, such as once a week, as described in your User's Manual.

The standards used for instrument calibration should be traceable to international or national measurement standards. If such standards do not exist, the basis for the calibration should be recorded. 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 either the NIST or the NPL 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 the instrument's standards are recalibrated. The uncertainty associated with calibrated values is also reported on each Certificate of Traceability. Replacement Certificates of Traceability may be obtained through HunterLab Technical Support if required.

As for the second part of the requirement, the period between calibration verifications by a HunterLab technician should be established based on the stability and usage of the instrument. HunterLab can make recommendations on verification intervals, but the Organization's individual needs will dictate the actual period chosen. HunterLab provides diagnostic and repair services, as well as instrument and tile recalibration.

If any diagnostic indicates a problem or the instrument otherwise malfunctions, it must be removed from service until the problem is corrected. Appropriate action concerning any product affected by measurements already made should be taken. Otherwise, HunterLab provides repair service for all its instrument models until five years have elapsed since last manufacture of the model. If repairs are extensive or no longer available, the instrument may be scrapped.

The instrument should be labeled or coded with an indication of its 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 should also indicate 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 Organization.

Access to adjustable settings that affect instrument performance should 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 Organization to label, cover, or otherwise inform users that tampering is unacceptable.

A system for handling, transporting, and storing the instrument 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.

## Reference

American National Standard ANSI/ISO/ASQ Q9001-2015 "Quality management systems— Requirements," American Society for Quality: Milwaukee, 2015.

## About HunterLab

HunterLab is the technology leader in color measurement solutions, providing instruments, software, knowledge and service to a wide variety of industries.

With over 5 decades of experience in more than 65 countries, HunterLab applies our leading edge technology to your products helping you measure and communicate color simply and effectively.

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