Applications Note

Insight on Color **Vol. 16, No. 4**

ISO 9001: 2000 Certification and Your HunterLab Instrument Part II. Documentation Requirements

This note provides additional information regarding Section 4.2 of ANSI/ISO/ASQ Q9001-2000, "Quality management systems—Requirements." Summary information was provided in Part I of this series of *Applications Notes* and will be quoted here. 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.

4.2 Documentation requirements

4.2.1 General: The quality management system documentation shall include...c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard.

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.

- 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 (in this case, a LabScan XE with Universal Software) is given below. Similar methods could be implemented for other types of instrument checks, standardization, and normal instrument operation.

  Repeatability Test

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

  1. If the LabScan XE was turned off over the weekend, turn the instrument on and allow it to warm it up for two hours. 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 2-inch port plate and standardize the instrument for the 1.75-inch area of view with UV filter nominal. Use the default 5 flashes per measurement.
  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.

For Additional Information Contact:

Technical Services Department
Hunter Associates Laboratory, Inc.
11491 Sunset Hills Road
Reston, Virginia 20190
Telephone: 703-471-6870
FAX: 703-471-4237
www.hunterlab.com