



With the volume of calibrations performed each year, calibration information has to be collected, managed and analyzed efficiently and consistently to satisfy regulatory requirements and make the most of limited resources. Built on a legacy of over 15 years developing calibration management software, Blue Mountain Regulatory Asset Manager offers the next generation of best-in-class features and functionality to specifically address the unique regulatory and productivity needs of calibration professionals.

PLANNING AND MANAGING WORK

While Blue Mountain Regulatory Asset Manager's work order system is available for calibration work, most metrologists prefer to manage their work with an instrument-centric approach. Within Blue Mountain Regulatory Asset Manager the metrologist can display a list of assets that meet specific query criteria, including calibration due dates and assigned person, and then proceed immediately to the calibrations on those instruments without the additional steps of completing and getting redundant approval on a work request. Recurring and planned calibration activity can be stored in event templates, containing such information as SOPs, task lists, measurement data templates, and a complete workflow, including work states and approval process. When an event is assigned to a specific asset, the frequency of the event and calibration standard type to use is recorded. The status of calibration work in process is available, flagging what jobs are on hold or in remediation and where out of tolerance or calibration failures have occurred.

COLLECTING MEASUREMENT DATA

When performing a calibration, the technician opens the calibration work record to access all the details needed for the task. The calibration professional then proceeds immediately to collecting measurement data without any set point setup required at the time of the calibration. In those instances where multiple readings are taken by set point, mean and standard deviation calculations are performed and limits can be placed on how far a single reading can vary from a set point's mean. Similar limits can be placed on how much a standard's actual reading can vary from the nominal set point value. Out of Calibration and Failed Calibration flags can then be automatically set by the software based on actual measurement data according to your tolerance levels.

All the details for the measurement collection are pre-configured for the recurring activity in a measurement data template. A single template is generally applied to many similar instruments, even if they are used across different operating ranges. The option to designate percent of operating range within the template, instead of specific set points, significantly enhances the template's flexibility. This template configuration includes warning levels relating to calibration, adjustment and process tolerances. When these tolerance levels are exceeded, alert flags are displayed and notifications can go out to specific individuals.

#	Nominal	Units	Standard	Instrument	Deviation	Warnings
1	15	PSI/PSI	14.7	15.1	0.4	● ...
2	75	PSI/PSI	75.3	81.4	6.1	● ...
3	135	PSI/PSI	135.1	135.2	0.1	● ...

#	Standard	Instrument	Deviation
1/1	14.7	15.1	0.4
2/1	75.3	81.4	6.1
3/1	135.1	135.2	0.1

Measurement data collection



REVERSE TRACEABILITY OF STANDARDS

Blue Mountain Regulatory Asset Manager offers best-in-class reverse traceability of standards, another key area of calibration compliance. Since any field can be designated as a report field, a reverse traceability report, configured to your exact needs, can be called up directly from the master standard record. This same list of instruments for a standard during a specific timeframe can also be brought up directly within the application for quick and flexible access to information required for remediation. Traceability can even extend to determining for which batches and tests the instrument was used.

The time and effort required to track standards used is minimized with the categorization of standards. When performing a calibration, the list of standards to choose from can be filtered to show just those with the combination of classification (i.e. temperature standard) and operating range designated for the task. Standards that have failed a calibration, are overdue for calibration, or whose Test Accuracy Ratio (TAR) does not meet a required threshold can be locked down to prevent assignment to new calibrations. The standard's measurement uncertainty, generally updated during its calibration, can be referenced whenever it is used in an instrument's calibration.

Standard Name	Hsmt. Class	Accuracy Ratio	Uncertainty	Due Date	Standard Class
STD-FLUKE-7438-1	Pressure 0-500 ...	4,00	0,356	10/29/2007	Pressure
STD-FLUKE-7438-2	Pressure 0-500 ...	2,00	0,356	10/25/2007	Pressure
STD-FLUKE-7438-3	Pressure 0-500 ...	4,00	0,356	9/28/2007	Pressure
STD-FLUKE-7438-4	Pressure 0-500 ...	4,00	0,356	9/26/2007	Pressure
STD-PRESSURE...	Pressure 0-500 ...	4,00	0,356	9/25/2007	Pressure
STD-PRESSURE...	Pressure 0-500 ...	4,00	0,35	8/31/2007	Pressure

Assigning Standards

WORKING SMARTER

The software's key performance indicator (KPI) reports analyze calibration efficiency by highlighting trends and opportunities for improved productivity. For example, a report can highlight instruments with a high incidence of calibration failure. Likewise, analysis of the out of tolerance information for specific instruments can provide data for determining a more efficient interval for calibrations. These reports can be tailored as needed and new reports for analyzing any information within the database can be generated.

To speed an asset's return to production and minimize downtime, Blue Mountain Regulatory Asset Manager facilitates the collaboration between calibration, maintenance and quality personnel. For example, a notification can be sent automatically to the calibration planner when maintenance work generates a need for calibration. This collaboration can be an important key to efficiently managing the validated state for equipment and processes.

The software's advanced electronic signature and routing functionality, part of the work flow system, significantly expedites the approval process while satisfying all 21 CFR Part 11 requirements. Integrated at all levels of the software, different approval paths can be configured for different instrument and event types where needed. By having all responsible individuals collaborate in a single application, faster communication reduces time spent in the approval process.