MICRO MOTION RECOMMENDED CALIBRATION PRACTICES FOR CORIOLIS METERS USED TO COMPLY WITH FDA 21 CFR PART 11

This document defines the official Micro Motion, Inc. "manufacturer-recommended best practice" to assist users in their compliance with Food & Drug Administration 21 CFR part 11. It is suggested that users retain a copy of this document in their compliance files.

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1. Initial Baseline Calibration:

All meters produced by Micro Motion are factory calibrated in a NIST-traceable laboratory. This water calibration has been proven to apply to all fluids, including gases (see AGA-11 / API MPMS Chapter 14.9, at www.aga.org). Calibration sheets are shipped with each meter, and a copy is retained by serial number at the factory. This documentation is sent with each meter, and a copy is retained at Micro Motion, Inc. Documentation is also available showing NIST and ISO17025 traceability.

2. In-use Calibration Technique and Frequency:

For existing applications: where the application warrants, Micro Motion recommends that meters with the 800 Enhanced Core Processor be upgraded to Smart Meter Verification (SMV). The upgrade may be done in-situ by a trained and factory certified Micro Motion Service Technician.

If the process does not warrant this investment, then Micro Motion recommends using traditional "wet-calibration" methods, such as "catch & weigh" or "master meter". A Micro Motion ELITE® meter is the recommended transfer standard (master meter). ***Once per 3 years*** is recommended, unless the application is highly corrosive (known material compatibility issues) and the meter is viewed as a "consumable". In those rare applications, once per year or more often is suggested.

New Applications: Micro Motion recommends the purchase and installation of meters with Smart Meter Verification (SMV). SMV is "manufacturer-recommended best practice" and can be run automatically while in operation as frequently as the user desires. We suggest a ***once per quarter verification*** to establish a robust set of data. In the unlikely event the meter were to "fail" the SMV, perform SMV two additional times, and if there are 3 out-of-spec data points, then a wet-calibration is warranted. Data shows that if the meter passes SMV, then it is within manufacturer specification, and a wet-calibration is not needed. Wet-calibration options include: a) NIST-traceable master meter, b) "catch-and-weigh", c) return to Micro Motion factory or d) a third party lab such as CEESI, SwRI, or equivalent.

Note that retrofits with the wireless Emerson THUM adapter can be used to remotely activate Smart Meter Verification and unlock trapped diagnostics useful for process troubleshooting.

For more information, please feel free to contact your local Sales Representative, or me directly.

Sincerely,

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