FAQ for FDA 21 CFR part 11

Recognition of Smart Meter Verification

Aug 2015 Tom O'Banion

1. How often do I run SMV?

   It is suggested that SMV be run once per quarter during normal operation. After a new meter is installed, it's often useful to run SMV several times to get a good set of initial data.

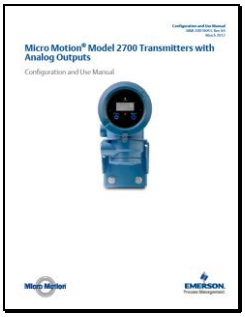
2. How do I record keep?

   The customer should create a Work Practice (SOP = Standard Operating Procedure) that specifies the steps to run SMV, and generate a report (electronic, paper, or both) that can be methodically filed by that meter's tag number.

3. What are the steps to execute?

   The specific steps to execute FDA-compliant SMV vary somewhat depending on whether the user chooses to run the test via faceplate, handheld communicator, ProLink or an AMS snap-on. Please see the appropriate transmitter manual, such as the 2700 shown below

   http://www2.emersonprocess.com/siteadmincenter/PM%20Micro%20Motion%20Documents/2700-Analog-Config-MMI-20019043.pdf



4. What does the FDA require?

   21 CFR part 11 generically describes following "best practice" when it comes to calibration or verifying the accuracy of the meter. Based on that, we've prepared a definitive set of guidelines which follow the EPA GHG work done a few years ago. We've had very good customer feedback and confirmation that as long as MMI has "irrefutable, engineering / test based proof" that SMV assures meter accuracy, it is FDA-compliant. FDA as such does not offer "approvals" but publishes guidelines and requirements which customers and vendors are expected to follow. Here is MMI's letter. You may find this as document #GI 002000 Rev A:

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

20 Jun 2015

1. **Initial Baseline Calibration:**

2. **In-use Calibration Technique and Frequency:**

EMERSON. Process Management

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Regarding record- keeping, AMS Device Manager can assist with this. Please review the screen shots contained in the customer facing ppt.

Customers tell us that using a system such as offered by OSIsoft PI for recordkeeping facilitates compliance. Data is kept by tag number for "pass / fail" criteria

5. How does E+H comply? What are the drawbacks? Other competitors?

FDA 21 CFR part 11 is generic enough that E+H and other vendors (including Rosemount Mag meter MV) comply, with proper procedures and record keeping. Thus, it is important to be skilled in presenting the differences between MMI SMV, E+H FieldCheck (80/83/84 transmitters) and HeartBeat (100/200 Coriolis and 400 Magmeter transmitter). Krohne's OptiCheck also likely complies (offered on Mag meter only)

6. What other agencies approve/accept SMV?

A growing list of third-party agencies and regulators recognize or approve SMV. These include (as of August 2015):

- AER Directive 17 (Alberta Energy Regulator for fiscal transfer of liquid petroleum)
- US EPA (40 CFR Part 98 for GreenHouse Gas)
- US EPA (40 CFR Part 75 for Acid Rain- coming in ~ late 2015)
- ISO 9001, Ch 7.6
- IEC/exida (for SIS)
- AGA-11 / API Ch 14.9 of MPMS (for Natural gas)
- Russia Pattern/Type Approval (via VNiiMS – coming Oct 2015) All metrology in Russia
- TTB (very similar to FDA- coming Sep 2015)

- API 20.2 (Allocation- final ballot in progress. Estimate Sep/Oct 2015)

For more complete information, please see Global Sales Portal or contact Tom O'Banion at tom.obanion@emerson.com

7. What are the recommended key points and process steps to follow when presenting the material to customers? (use SMV video and 2/3 slides on Theory of Operation-springs example)

   It is good to open the conversation with a statement that we're hear to learn about how SMV might benefit the customer's operation (cost, time, and FDA compliance), and ask questions about current work practices.

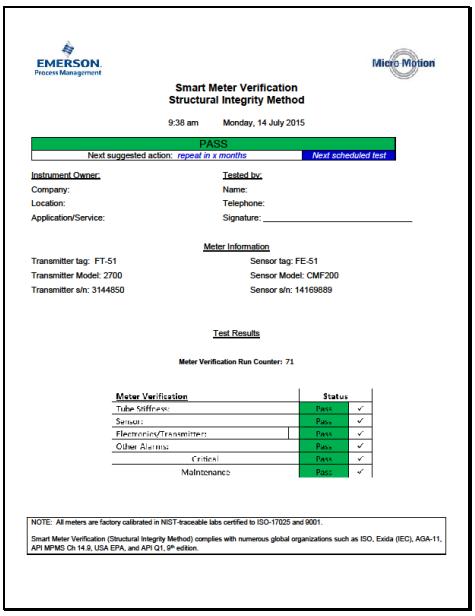
   Then, many sales reps will choose to share the "stick figure" YouTube video

   (https://www.youtube.com/watch?v=Kmp7eZaF3KM&list=PLTI6uY3auTkYPpBHR8_zsl2p7YZe8qaUB)

   The meter stays in the line, and the process can continue operating. SMV is a great diagnostic tool for process troubleshooting as well as providing a robust "data trail" for FDA compliance in case of an audit.

   Discuss with the customer about helping them re-write their SOP (Standard Operating Procedure) based on SMV.

   It's also very helpful to demonstrate how easy it is to run SMV. The pass/fail results are very definitive and do not require an expert to interpret them. I generally share the SMV report form with them. Please share that a simpler, more visually appealing report form is under development. We anticipate it will be released around October of 2015. The user will have the option of choosing the current or new report form. A sample is shown below:



EMERSON. Process Management

Micro Motion

Smart Meter Verification
Structural Integrity Method

9:38 am Monday, 14 July 2015

PASS

Next suggested action: *repeat in x months* | *Next scheduled test*

Instrument Owner:
Company:
Location:
Application/Service:

Tested by:
Name:
Telephone:
Signature: _____

Meter Information

Transmitter tag: FT-51
Transmitter Model: 2700
Transmitter s/n: 3144850

Sensor tag: FE-51
Sensor Model: CMF200
Sensor s/n: 14169889

Test Results

Meter Verification Run Counter: 71

Meter Verification	Status	
Tube Stiffness:	Pass	✓
Sensor:	Pass	✓
Electronics/Transmitter:	Pass	✓
Other Alarms:	Pass	✓
Critical	Pass	✓
Maintenance	Pass	✓

NOTE: All meters are factory calibrated in NIST-traceable labs certified to ISO-17025 and 9001.

Smart Meter Verification (Structural Integrity Method) complies with numerous global organizations such as ISO, Exida (IEC), AGA-11, API MPMS Ch 14.9, USA EPA, and API Q1, 9th edition.

8. How does this apply to installed base? What is the upgrade program?

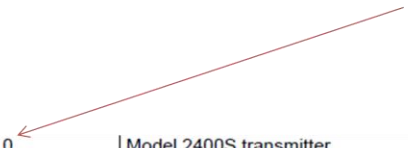
Our installed base with 800 ECP can be easily upgraded with SMV in the field without removing the sensor. For older meters where SMV would greatly benefit the customer, we suggest that the older meter be used elsewhere and a new meter with SMV procured. Talk to your local Sales Management about possibly offering an incentive for the customer to make this change.

700 vs 800 Core Processor Options

	9-wire	700 CP	800 CP
When made	1992-today	1999-today	2006-today
Sensor family	All except for T	All	All except for T-series
Where CP appears in the model code	n/a	CMF100M328N_AUEZZZ	
Software upgrade possible?	N	N	Y
Sensor upgrade?	Y	Y	N

An example model code is shown below to determine SMV upgradability

- CMF100M328N_AUEZZZ



0	Model 2400S transmitter
1	Extended mount Model 2400S transmitter
2	4-wire polyurethane-painted aluminum integral enhanced core processor for remote mount transmitters
3	4-wire stainless steel integral enhanced core processor for remote mount transmitters
4	4-wire polyurethane-painted aluminum integral extended mount enhanced core processor for remote mount transmitters
5	4-wire extended mount stainless steel integral enhanced core processor for remote mount transmitters
Q	4-wire polyurethane-painted aluminum integral core processor for remote mount transmitters
A	4-wire stainless steel integral core processor for remote mount transmitters
J[4]	2-wire integrally mounted Model 2200S transmitter
U[4]	2-wire extended Model 2200S transmitter
R	9-wire polyurethane-painted aluminum junction box
S	9-wire 316L stainless steel junction box
H	9-wire extended mount polyurethane-painted aluminum junction box
T	9-wire extended mount stainless steel junction box

9. What about T-Series sensors?

Current T-series is not SMV-enabled, but future plans include a product update that will include the new feedthrough and 800 ECP. SMV will then become an option on T-series. Numerous customers are interested in this!

10. How do I position the products for projects? H-Series and CMFS, etc.

First determine which meters are in the hygienic portion of the plant or facility. If 3-A or EHEDG is not required on the meter, you can select from virtually any of our products (check of course for requirements for hygienic style process connections). For the hygienic portions, CMFS010 and 015 are options. At this time the larger sensors do not have hygienic ratings. H-series is a good option and of course has SMV as a feature. T-series would not be an option where SMV is needed, but may be used for it's straight-through, cleanable, hygienic design.

11. Questions and approach for F&B and Life Sciences / Pharma

To prepare for the FDA-SMV sales call, we suggest you

- Refresh your understanding of SMV and MMI mass flow theory
- Review the definitions of Calibration, Verification, and Validation
- Watch the SMV and Zero Verification Tool "stick figure" YouTube videos, at https://www.youtube.com/watch?v=Kmp7eZaF3KM&list=PLTI6uY3auTkYPpBHR8_zsl2p7YZe8qaUB and https://www.youtube.com/watch?v=dY_ENuE1H1k
- Determine current calibration practices for the customer's flowmeters, and how their costs are estimated. An example provided by Joe LaFauci at Teva Pharmaceuticals is shown below

Data:

50 meters per year

8 each hours to remove, clean, calibrate and reinstall

$100/hr for skilled technical (burdened)

Calculation:

50 meters/yr x 8 hrs/meter x $100/hr = $40,000 per year.
