

SAMPLE PREP MEETS ISO17025

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Sample Prep Meets ISO17025

- Have been accredited in FEED program over 2 years
- The Sample Prep section of the MDA laboratory is not in conformance with the ISO17025 standard
- Corrective Action
- Incorporate ISO elements into sample prep SOPs and procedures, determine critical equipment, demonstrate validity of results, expand recordkeeping and others
- We are not the only lab will facing this challenge

ISO 17025 requirements

- Requires sampling plan and procedures-YES
- Based on appropriate statistical methods-2008 AAFCO manual
- Process shall address factors to be controlled to ensure validity of results-NO
- Procedures for recording relevant data-NO

Checklist

SCOPE Expansion requirements - Prep methods

Action	Responsible person(s)	Date completed	Comments
Official Method Audit with AAFCO manual	Robin		
Method Rewrite for ISO	Robin		
List of critical equipment	Robin & Tyler	6/21/2016	
Critical equipment verification (if new) ie: columns, extract equip			Tyler is ordering sieves for verification
List of critical supplies	NA	NA	
Critical supplies verification (if new) i.e.: solvents, standards	NA	NA	
Glassware verification (if new) i.e.: any glassware not ISO verified	NA	NA	
Instrument operating parameters established	??		In prep methods?
Method Validation Data	Nicole's spreadsheet		
Measurement Uncertainty budget	In analytical methods		
Method Information form	Tyler		Will use labworks form/ Update!
Training Authorizations complete	Tyler		
Full Method audit	Becca		
Passing PT result	NA	NA	

Sample Prep Meets ISO17025

- Staff trained and authorized-YES
- Traceability records-NO
- Critical equipment-NO
- Demonstration of Proficiency-?
- Measurement Uncertainty-YES
- Quality Control-?



Trained and Authorize

- Staff training records:
 - Handling samples
 - Equipment use
 - Splitting of samples
 - Grinding of samples
 - Storage



Authorization records are kept!

Traceability

- Identify staff who splits
- Identify staff who grinds
- Identify equipment used for splitting and grinding
- Identify split number
- Update SOP
- Maintain records



Sample Login Claim Summary Report

Printed on: 6/27/2016

Sample No.	Type	Description	Result Name	Claim Value	Units
AB61386	Specialty Fertilizer	25-10-10			Onits
•			Available P2O5 Claim	10.0	%
			Soluble K2O Claim	10.0	%
			Sulfur Claim	6.0	%
			Total Nitrogen Claim	25.0	%
AB61387	Specialty Fertilizer	Split: 10 date / Lord 10 Notation Rotary Feeder Rotary Divider, Rotary Feeder 16-16-16	grind: All / Ninja, Coffee GritSch, Retsch,	nder, Stand up Mill, Blender, Knife Mill	Wiley
			Available P2O5 Claim	16.0	%
			Soluble K2O Claim	16.0	%
			Sulfur Claim	6.0	%
		4-28-16	Total Nitrogen Claim	16.0	%
		Riffle Splitter, Rotary Divider Rotary Feeder	grind: / / / / / / / / / / / / / / / / / / /	in Jay nder, Stand up Mill, Blender, Knife Mill	Wiley

Critical Equipment

- Identify Critical Equipment
- Locate supporting paperwork and manuals
- Establish Maintenance program
- Establish Calibration/Verification program



Equipment

Sampl	e Prep	Equipment	List
- ap.	F	-9	

Manufacturer N	ame Type Identification	Unique Identifier	Serial Number	Location of Equipment
Gilson	Grated Riffle Splitter SP-2.6	Riffle Splitter	N/A	Room 1B
Nutri Ninja	BL480	Ninja	N/A	Room 1B
Krups	F203	Coffee Grinder	F203425-6W0-4913R	Room 1B
Retsch	SR 300 ROSTFREI	Stand up mill	91103005	Room 1C
Thomas Scient	ific Wiley Mill Model 4	Wiley	90101	Room 1C
Fritsch	Rotary Sample Divider Laborette 27	Rotary Divider	27.1417602	Room 1C
Fritsch	Rotary Vibratory Feeder Laborette 24	Rotary Feeder	24.0040/02850	Room 1C
Fritsch	Pulverisette 14 Mill	Fritsch	14.3000/01499	Room 1C
Retsch	ZM 200 Mill	Retsch	1212170242	Room 1C
Sunbeam	Model 2774	Blender	N/A	Room 1B
Retsch	GM 300	Knife Mill	1212070328	Room 20

Still need to include:

- Calibration/verification information
- Verification acceptance criteria
- Verification timeline

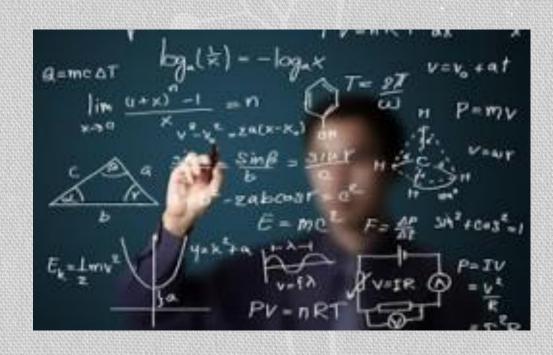
Proficiency Sample

- Is it feasible?
- Sample PREP portion
- Incorporate into AAFCO



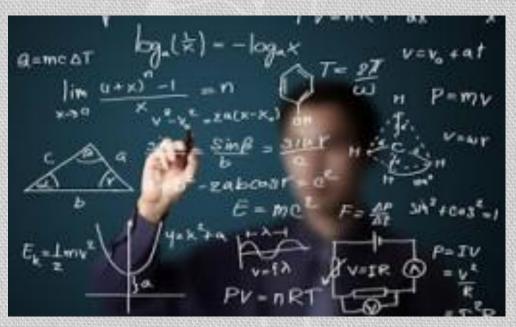
Measurement Uncertainty

- Measured and included in method
- Maintain split records
- Calculate %RPD periodically
- Good performers
- Bad performers



Quality Control

- Maintain split records
- Calculate %RPD periodically
- May be used to establish limits
- Others to be determined



Conclusions

- Unique
- Don't forget Sample PREP
- Critical process that affects result
- ISO17025 considerations

Credits

- Study design team:
 - Heidi Hickes
 - Robin Johnson
 - Becca Dellwo
- LIMS support:
 - ·Soo Yoon
- Presentation edits:
 - Nichole Chimbos