

ISO 17025 Accreditation/Quality Management Systems Panel Discussion

AAFCO 2014 Annual Meeting

Laboratory Methods & Service Committee

Sacramento, CA

July 26, 2014



Management Review

Presented by Teresa Grant

North Carolina Department of Agriculture & Consumer Services



Relevant section of the standard

4.2.2 Management System

4.10 Improvement

4.1.1 Corrective Action

4.13.1.1 Control of Records

4.15 Management Reviews



During the course of an annual Management Review, the following information and/or data is presented for review and discussion as it complies with the ISO/IEC 17025 Section 4.15.1. This information generally includes items as it pertains to our accrediting body, customers, policies, quality management system, and laboratory testing.

- Suitability of policies and procedures
- Reports from managerial and supervisory personnel
- Recent internal audit findings
- Corrective and preventive actions
- Assessments by external bodies
- Results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of work
- Customer feedback
- Complaints
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training
- Management objectives, goals and action plans for the coming year
- Action Items

Management Review Agenda

Attendees:

- Changes to type and volume of work; future direction of FDPD Lab –
- Training – plans, goals, objectives – document individually in work plans; matrix documenting ongoing competency and cross-training also supports this.
- Quality Objectives
- Discussion of review topics (these need to include review of audit findings not covered in Sept Management Review meeting – refer to report for specific audit topics to be covered)
 1. Section 4.13 Control of Lab Records
 - a. General comments -
 - b. Internal audit results – QA
 2. Section 5.4.7 Protection of Electronic Data
 - a. General Comments –
 - b. Internal audit results – QA
 3. Report on audit of QMS.023.004 – QA
 4. Additional discussions:



Management Review Agenda (continued)

- Sample Rejections: 2/1/14-4/30/14
- NCRs: 2/1/14-4/30/14
- PARs: 2/1/14-4/30/14
- PTs: 2/1/14-4/30/14
- Status of Action Items from last meeting
- Status of Internal Audits -
- Status of “Annual QMS Tasks” (see end of Management Review Planners)
- Continuous improvement

Management Review Agenda (continued)

Assignments for Next Meeting:

ISO clause 4.6 (QMS.006)

ISO clauses 4.7, 4.8 (QMS.007)

ISO clause 4.13 (QMS.011)

<u>Related Clause</u>	<u>Action Item</u>	<u>Assigned To</u>	<u>Target Date</u>	<u>Status</u>
NEW ACTION ITEMS (Q4) 2014				
Quality Objective				

Management Review Opening Comments - Date

➤ Budget

Total spent			
Total available			
Remaining			
Save for repairs, incidental expenses			
Available			

➤ Staffing

Vacancies	Status

➤ Facility updates

➤ LIMS updates

➤ Training Dates

Name of class	Trainer	Location	Attendee



Management Review Preparation Planner

(To be completed by Quality & Managerial Personnel)

Name: _____

Meeting Date: _____

Meeting Preparation

Read the QMS procedure(s) indicated by checkboxes. In addition, read that section of the Quality Manual (FDPD-QMS.001) and the ISO 17025/AOAC Guidelines. Use the Comment Sections below to address suitability and effectiveness for each assigned topic. Use the drop down list at the start of each Comment section to identify the topic.

Assigned Topics:

- 4.1 Organization (QMS.002)
- 4.2 Management
- 4.3 Document Control (QMS.003)
- 4.4 Review of Requests, Tenders, Contracts (QMS.004)
- 4.5 Subcontracting
- 4.6 Purchasing Services & Supplies (QMS.006)
- 4.7 Service to the Customer (QMS.007)
- 4.8 Complaints (QMS.007)
- 4.9 Control of Nonconforming Testing (QMS.009)
- 4.10 Improvement (QMS.010)
- 4.11 Corrective Action (QMS.009)
- 4.12 Preventive Action (QMS.010)
- 4.13 Control of Records (QMS.011, QMS.019)
- 4.14 Internal Audits (QMS.012)
- 4.15 Management Review (QMS.013)
- 5.1 General
- 5.2 Personnel (QMS.014)
- 5.3 Accommodation & Environmental Conditions & AOAC Appx. B (QMS.015 & subordinates)
- 5.4 Test Methods & Method Validation
- 5.4.2 Selection of Methods (QMS.016)
- 5.4.3-5.4.5 Method Validation (QMS.018)
- 5.4.6 Estimation of Measurement Uncertainty (QMS.017)
- 5.4.7 Control of Data (QMS.019, QMS.025.001)
- 5.5 Equipment & AOAC Appendix A (QMS.020 & subordinates)
- 5.6 Measurement Traceability (QMS.021 & subordinates)
- 5.7 Sampling
- 5.8 Handling of Test Items (QMS.023)
- 5.9 Ensuring the Quality of Test Results (QMS.024 & subordinates)
- 5.10 Reporting the Results (QMS.025)
- A2LA Advertising Policy (QMS.026)



Management Review Preparation Planner (Continued)

QA – Record Annual Document Review

Comments Section

Keep in mind the definition of “Effective”: The degree to which objectives are achieved and the extent to which targeted problems are solved.

Choose an item

Is the policy both **suitable and effective**? Why/why not?

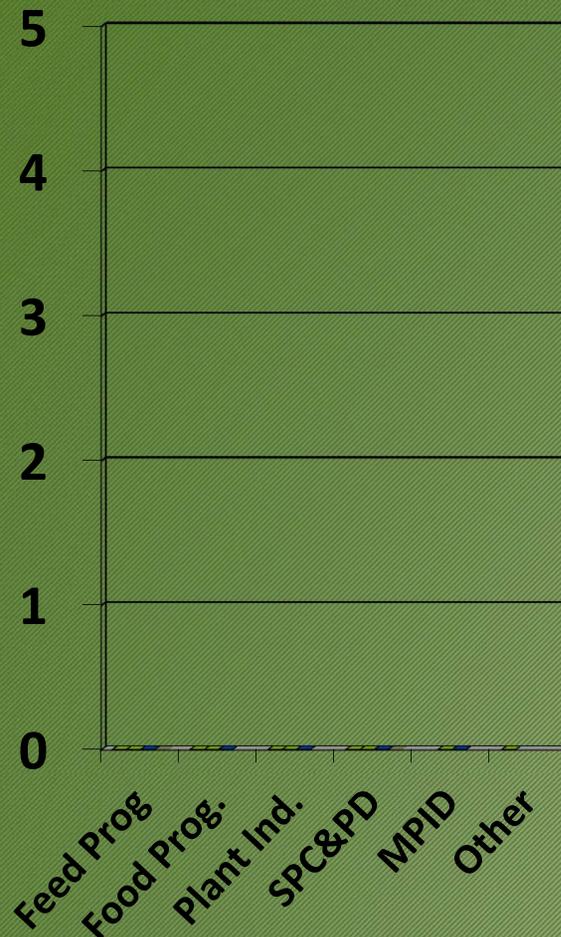
Is the procedure both **suitable and effective** for our lab? Why/why not?

[Note: this is more than just an audit against ISO or the Quality Manual – does the process in this procedure work here? Is it the right process for our lab?]

Comments/corrections for the DRR list (be specific):

Feedback and Complaint Summary

(2/1/14 – 4/30/14)



- 0 new records in Database
- How many led to NCR? 0
- How many led to PAR? 0
- How many were positive? 0
- Complaints? 0
- Inquiries? 0



■ unsolic. ■ complaint ■ solic. ■ inq.

Microsoft Access

Home Create External Data Database Tools

Views Clipboard Font Rich Text Records Sort & Filter Window Find

Feedback and Complaints

Record #: (New)

Date:

Customer:

If other, please specify:

Phone:

Phone:

Email:

Email:

Person submitting form:

This is: Unsolicited Feedback Solicited Feedback Complaint Customer Inquiry

Affected Lab Section:

Reason:

Describe feedback/complaint with as much detail as possible, including dates/sample numbers if relevant

Save Record Add New Record [Send Notification Email](#) Close Form

For Supervisors Use Only

Lab Supervisor:

Lab Comments

Resolution/Follow-up

Record: 106 of 106 No Filter Search

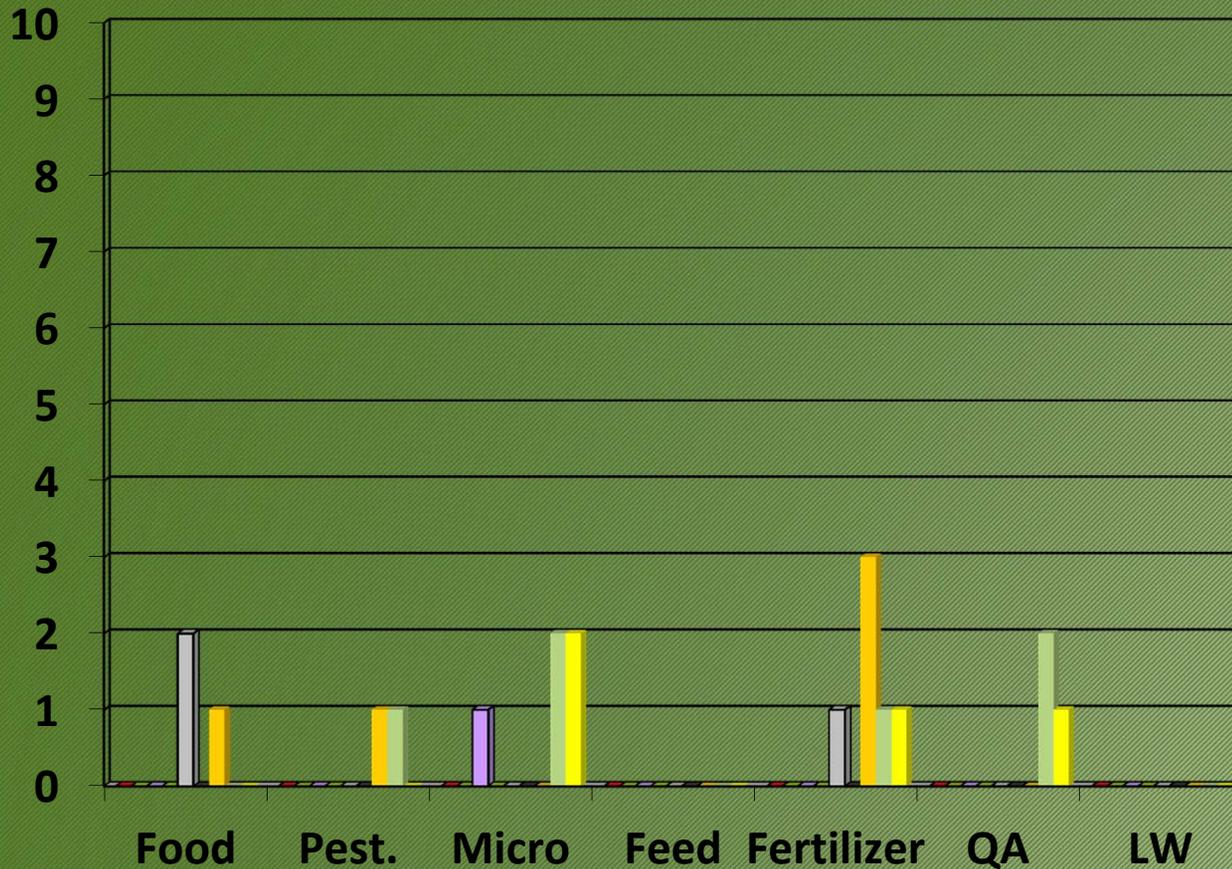
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NCRs by Lab

(2/1/14 - 4/30/14)

	Total NCRs	Audit	Self Report
Food	3	0	2
Pest	2	1	1
Micro	5	0	5
Feed	3	0	3
Fert.	6	0	3
QA	3	0	2
LW	3	3	0



Total = include # already open;
 Audit/Self Report = # initiated during this time period

- Incor. Data
- Supplies
- Eqp
- Contam.
- QC
- Customer
- PT
- Doc



PARs

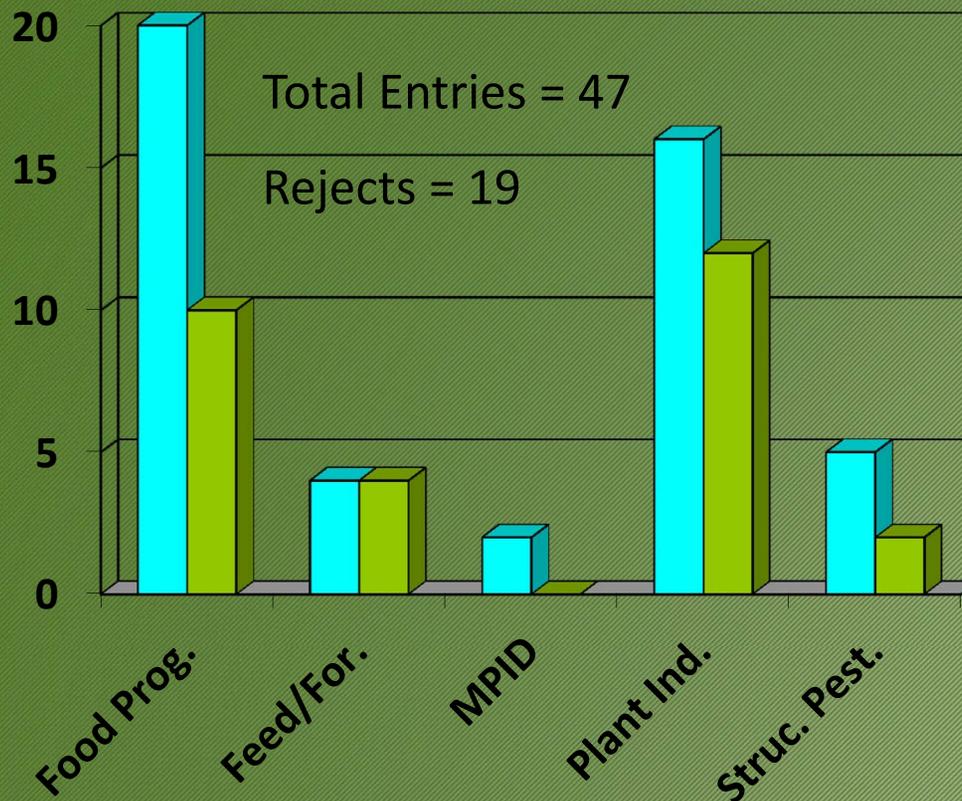
(2/1/14 - 4/30/14)

Section	# <u>Total</u> PARs submitted	Topics	Record numbers
Fert	2	Xxxxxxx YYYYYYY	14-133; 14-136
Food	1	zzzzzzzzz	14-139
Micro	1	aaaaaaaaa	14-129
Pest Res	0		
Feed/Forage	2	Bbbbbbb ccccccc	14-134; 14-138
QA	1	ddddddd	14-135
LW	2	Eeeeeeee ffffffffffff	14-128, 14-131,

Sample Disposition Records

Totals by Customer

(2/1/14 – 4/30/14)



Reason for Entry	# Entries for that Reason
Sample # or # subs does not match transcript	1
Leaking/spilling	6
Insufficient amount	7
Security seal broken	2
Other	31



■ Total Sample Entries

■ Samples Tested

Microsoft Access

Home

Clipboard: Paste, Cut, Copy

Font: [Font Face], [Size], [Color], [Bold], [Italic], [Underline], [Text Color], [Background Color], [Numbered List], [Bulleted List], [Decrease Indent], [Increase Indent], [Align Left], [Align Center], [Align Right], [Justify]

Rich Text: [Text Color], [Background Color], [Text Size], [Text Color], [Background Color], [Text Size], [Text Color], [Background Color], [Text Size]

Records: Refresh All, New, Save, Delete

Sort & Filter: Filter, Advanced, Toggle Filter

Window: Size to Fit Form, Switch Windows

Find: Find, Replace, Go To, Select

SampleDispositionForm

SECTION A

Please Fill Out All Fields in This Section

Date: [Date Picker] Form Filled Out By: [Text Box] Customer: [Dropdown Menu]

Sample ID: [Text Box] Inspector ID/Name: [Text Box]

Sample Description: [Text Box]

SECTION B

Check a box to indicate what is wrong with the sample. Not all criteria apply to every lab area or test. Add comments at the end of this section if necessary.

<input type="checkbox"/> Missing Transcript	<input type="checkbox"/> Security seal broken	<input type="checkbox"/> Samples with different lot codes in the sample set (microbiology)
<input type="checkbox"/> Illegible Transcript	<input type="checkbox"/> Sample not in bag/bottle	<input type="checkbox"/> Package says "keep refrigerated," but sample arrived frozen
<input type="checkbox"/> No sample number on sample	<input type="checkbox"/> Insufficient sample amount	<input type="checkbox"/> Sample received more than 1 day post collection (microbiology)
<input type="checkbox"/> Sample number does not match transcript	<input type="checkbox"/> Sample spoiled / rotten	<input type="checkbox"/> Sample received later than 2 days past the "sell by" date (microbiology)
<input type="checkbox"/> Subs numbers do not match transcript	<input type="checkbox"/> Frozen / melted sample	<input type="checkbox"/> Adulterated Temp [Text Box] C
<input type="checkbox"/> Number of samples/subs does not match transcript	<input type="checkbox"/> Leaking / spilling sample	Describe if necessary: [Text Box]
<input type="checkbox"/> Other: [Text Box]	Please briefly indicate a problem and explain below if needed	

Comments: [Text Box]

Record: 1 of 1 No Filter Search

Form View Num Lock

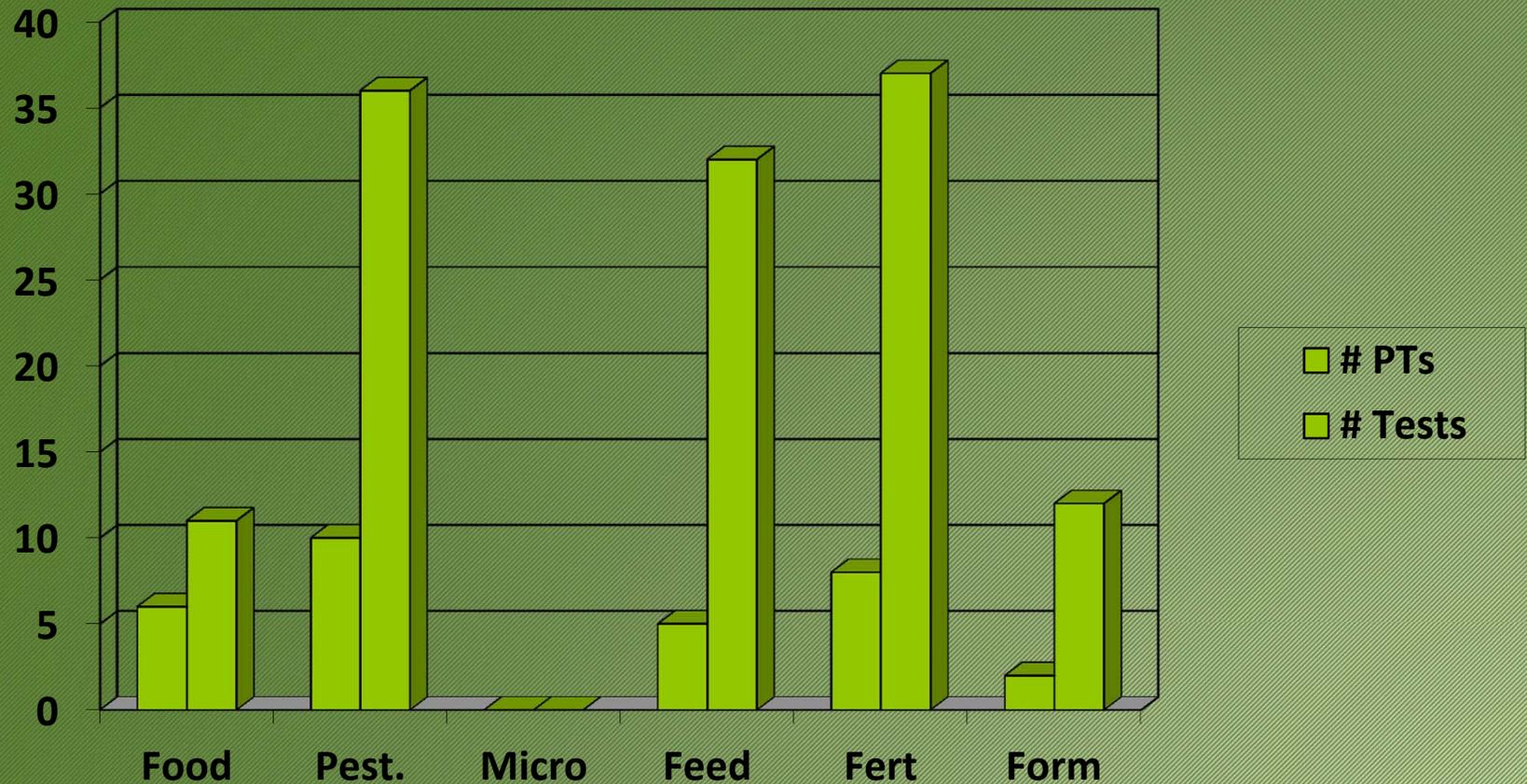
Inbox - Microsoft ... Microsoft Access ... 1:46 PM 7/14/2014



PT Summary

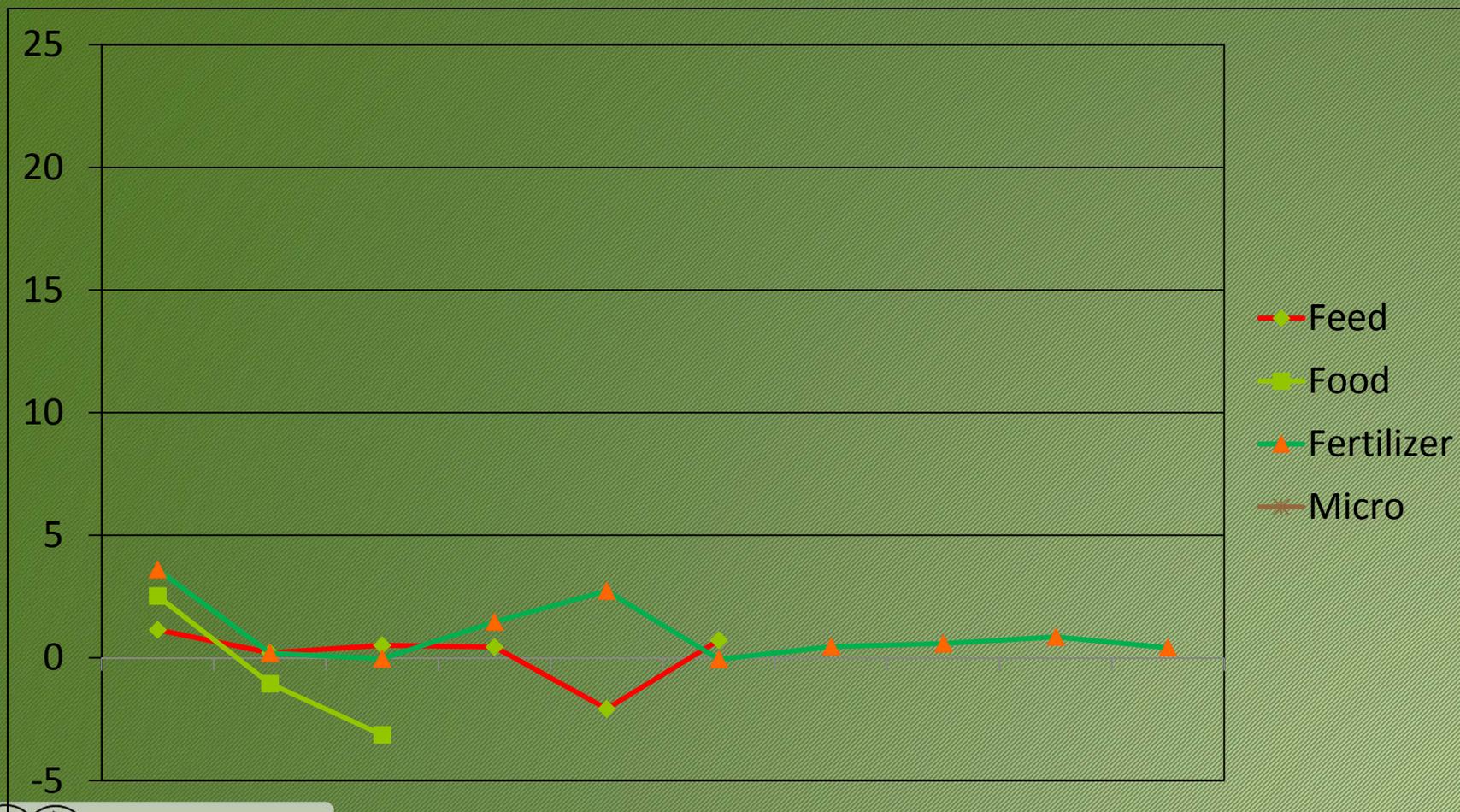
(2/1/14 – 4/30/14) Results back from Provider)

[Analytes counted multiple times if they appeared in multiple PTs]



Z-scores by Lab Section

(2/1/14 – 4/30/14)



Feed Program- Laboratory Customer Meeting Date, 2014

Attendance:

Email distribution:

1) BSE Grant

- Sample Collection & Testing –
- AAFCO meeting

2) Contracts – reviewed every two years – Feed March 2014

3) LIMS Reports –

4) Receiving –

- Sample Dispositions (from the *lab's* database) 1/17/14-2/9/14 none to report

SD #	Date	Sample #	Sample Descr.	Problem	Tested? Y/N

5) Other Sample Issues –

Additional Discussion:

Action Items and Assignments for next meeting:

Complete updates to contracts during meeting.

Action item	Assigned to	Due date	Completed



Technician

KRR	ISO 17025 Accreditation Maintenance and Continuous Improvement [QMS Documentation, Non Conformities, Corrective Actions, Preventive Actions, Audits]
G	<p>Support continuous improvement by identifying at least 1 idea [includes ideas passed along from supervisor or other lab staff].</p> <p>Examples of ideas include:</p> <ul style="list-style-type: none"> ◆ improve the quality management system; ◆ improve understanding or interpretation of quality documentation; ◆ submit and develop preventive action [PAR] suggestions ◆ maximize efficient and effective use of personnel, equipment or lab space by optimizing use of personnel work hours, increasing run time on equipment, altering lab space, moving equipment; ◆ minimize testing turnaround time through identifying, investigating and addressing the cause of bottlenecks, delays or disruption to work flow; ◆ improve support to customer; ◆ reduce cost of testing [consumables, chemicals, standards, kits, glassware, optimized batching, etc] ◆ reduce cost of equipment maintenance ◆ improve safety
VG	Support continuous improvement by assisting Supervisor or assigned team with planning and/or implementing section ideas.
O	VG plus Support continuous improvement by identifying at least 2 ideas [includes ideas passed along from supervisor or other lab staff] <u>and</u> assisting Supervisor or assigned team with planning and/or implementing section ideas.

Technician	
KRR	Training
G	<p>Complete training as required per FDPD-QMS.014 Training and Competence, attend scheduled training sessions, complete reading assignments per Document Transmittal Notices [DTN] from QA, maintain personal training database and complete required Demonstrations of Competence.</p> <p>No more than 2 incidences of not attending scheduled training sessions, completing reading assignments, maintaining training matrix, completing Demonstration of Competence or completing QMS or lab section training requirements.</p> <p>Attended other training as assigned, such as vendor training.</p> <p>After training opportunities / classes are completed, must submit a brief report describing the take-away points to supervisor</p>

KRR	Training (continued)
VG	<p>Good level plus conducts training of others as assigned by supervisor or QA.</p> <p>No more than 1 incidence of not completing QMS or lab section training requirements.</p> <p><u><i>Proactively seeks one technical training opportunities from the following</i></u></p> <ul style="list-style-type: none"> -vendor classes or webinars association, government or other sponsor classes -online training - reads a book - reads 2 or more articles = 1 training <p>[all above options must be approved by Supervisor]</p> <p>After training is completed, must submit a brief report describing the take-away points to supervisor</p>

KRR	Training (continued)
O	<p>Very Good level plus volunteers to train others or develop sections for the lab section training manual or other example of proactive contribution to lab training program.</p> <p>No incidences of not completing QMS or lab section training requirements.</p> <p><u><i>Proactively seeks two technical training opportunities from the following</i></u></p> <ul style="list-style-type: none"> -vendor classes or webinars -association, government or other sponsor classes -online training - reads a book - reads 2 or more articles = 1 training <p>[all above options must be approved by Supervisor]</p> <p>After training is completed, must submit a brief report describing the take-away points to supervisor.</p>