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
Assignments for Next Meeting:

- ISO clause 4.6 (QMS.006)
- ISO clauses 4.7, 4.8 (QMS.007)
- ISO clause 4.13 (QMS.011)

<table>
<thead>
<tr>
<th>Related Clause</th>
<th>Action Item</th>
<th>Assigned To</th>
<th>Target Date</th>
<th>Status</th>
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**NEW ACTION ITEMS (Q4) 2014**

- Quality Objective
### Management Review Opening Comments - Date

#### Budget

<p>| | |</p>
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<tr>
<td>Total spent</td>
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<tr>
<td>Total available</td>
<td></td>
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<tr>
<td>Remaining</td>
<td></td>
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<tr>
<td>Save for repairs, incidental expenses</td>
<td></td>
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<tr>
<td>Available</td>
<td></td>
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#### Staffing

<table>
<thead>
<tr>
<th>Vacancies</th>
<th>Status</th>
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#### Facility updates

#### LIMS updates

#### Training Dates

<table>
<thead>
<tr>
<th>Name of class</th>
<th>Trainer</th>
<th>Location</th>
<th>Attendee</th>
</tr>
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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)  
4.3 Document Control (QMS.003)  
4.5 Subcontracting  
4.7 Service to the Customer (QMS.007)  
4.9 Control of Nonconforming Testing (QMS.009)  
4.11 Corrective Action (QMS.009)  
4.13 Control of Records (QMS.011, QMS.019)  
4.15 Management Review (QMS.013)  
5.2 Personnel (QMS.014)  
5.4 Test Methods & Method Validation  
5.4.3-5.4.5 Method Validation (QMS.018)  
5.4.7 Control of Data (QMS.019, QMS.025.001)  
5.6 Measurement Traceability (QMS.021 & subordinates)  
5.8 Handling of Test Items (QMS.023)  
5.10 Reporting the Results (QMS.025)  
4.2 Management  
4.4 Review of Requests, Tenders, Contracts (QMS.004)  
4.6 Purchasing Services & Supplies (QMS.006)  
4.8 Complaints (QMS.007)  
4.10 Improvement (QMS.010)  
4.12 Preventive Action (QMS.010)  
4.14 Internal Audits (QMS.012)  
5.1 General  
5.3 Accommodation & Environmental Conditions & AOAC Appx. B (QMS.015 & subordinates)  
5.4.2 Selection of Methods (QMS.016)  
5.4.6 Estimation of Measurement Uncertainty (QMS.017)  
5.5 Equipment & AOAC Appendix A (QMS.020 & subordinates)  
5.7 Sampling  
5.9 Ensuring the Quality of Test Results (QMS.024 & subordinates)  
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
NCRs by Lab
(2/1/14 - 4/30/14)

<table>
<thead>
<tr>
<th>Category</th>
<th>Total NCRs</th>
<th>Audit</th>
<th>Self Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td>3</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Pest</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Micro</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Feed</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Fert.</td>
<td>6</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>QA</td>
<td>3</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>LW</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Section</th>
<th># Total PARs submitted</th>
<th>Topics</th>
<th>Record numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fert</td>
<td>2</td>
<td>Xxxxxx</td>
<td>14-133; 14-136</td>
</tr>
<tr>
<td></td>
<td></td>
<td>YYYYYY</td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td>1</td>
<td>zzzzzzzzz</td>
<td>14-139</td>
</tr>
<tr>
<td>Micro</td>
<td>1</td>
<td>aaaaaaaaa</td>
<td>14-129</td>
</tr>
<tr>
<td>Pest Res</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feed/Forage</td>
<td>2</td>
<td>Bbbbbbbbb</td>
<td>14-134; 14-138</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ccccccccc</td>
<td></td>
</tr>
<tr>
<td>QA</td>
<td>1</td>
<td>ddddddddd</td>
<td>14-135</td>
</tr>
<tr>
<td>LW</td>
<td>2</td>
<td>Eeeeeeee</td>
<td>14-128, 14-131</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ffffffffffffffff</td>
<td></td>
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</tbody>
</table>
Sample Disposition Records
Totals by Customer
(2/1/14 – 4/30/14)

- Total Entries = 47
- Rejects = 19

<table>
<thead>
<tr>
<th>Reason for Entry</th>
<th># Entries for that Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample # or # subs does not match transcript</td>
<td>1</td>
</tr>
<tr>
<td>Leaking/spilling</td>
<td>6</td>
</tr>
<tr>
<td>Insufficient amount</td>
<td>7</td>
</tr>
<tr>
<td>Security seal broken</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>31</td>
</tr>
</tbody>
</table>

Total Sample Entries: 0
Samples Tested: 5
SECTION A
Please Fill Out All Fields in This Section

- Date
- Sample ID
- Sample Description
- Form Filled Out By
- Customer
- Inspector ID/Name

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.

- Missing Transcript
- Illegible Transcript
- No sample number on sample
- Sample number does not match transcript
- Sub numbers do not match transcript
- Number of sample/subject does not match transcript
- Security seal broken
- Sample not in bag/bottle
- Insufficient sample amount
- Sample spoiled/rotten
- Frozen/mailed sample
- Leaking/spilling sample
- Samples with different lot codes in the sample set (microbiology)
- Package says "keep refrigerated," but sample arrived frozen
- Sample received more than 1 day post collection (microbiology)
- Sample received later than 2 days past the "sell-by" date (microbiology)
- Altered Temp
- Other

Please briefly indicate a problem and explain below if needed.

Comments
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

<table>
<thead>
<tr>
<th>SD #</th>
<th>Date</th>
<th>Sample #</th>
<th>Sample Descr.</th>
<th>Problem</th>
<th>Tested? Y/N</th>
</tr>
</thead>
<tbody>
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5] **Other Sample Issues** –
**Additional Discussion:**
**Action Items and Assignments** for next meeting:
*Complete updates to contracts during meeting.*

<table>
<thead>
<tr>
<th>Action item</th>
<th>Assigned to</th>
<th>Due date</th>
<th>Completed</th>
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**AAFCO**
Association of American Feed Control Officials
<table>
<thead>
<tr>
<th>Technician</th>
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<tbody>
<tr>
<td><strong>KRR</strong> ISO 17025 Accreditation Maintenance and Continuous Improvement [QMS Documentation, Non Conformities, Corrective Actions, Preventive Actions, Audits]</td>
</tr>
</tbody>
</table>
| **G** Support continuous improvement by identifying at least 1 idea [includes ideas passed along from supervisor or other lab staff]. Examples of ideas include:  
  ♦ 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 |
<p>| <strong>VG</strong> Support continuous improvement by assisting Supervisor or assigned team with planning and/or implementing section ideas. |
| <strong>O</strong> VG plus Support continuous improvement by identifying at least 2 ideas [includes ideas passed along from supervisor or other lab staff] and assisting Supervisor or assigned team with planning and/or implementing section ideas. |</p>
<table>
<thead>
<tr>
<th>KRR</th>
<th>Training</th>
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<tbody>
<tr>
<td>G</td>
<td>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. 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. Attended other training as assigned, such as vendor training. After training opportunities / classes are completed, must submit a brief report describing the take-away points to supervisor</td>
</tr>
<tr>
<td>KRR</td>
<td>Training (continued)</td>
</tr>
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</tr>
<tr>
<td>VG</td>
<td>Good level plus conducts training of others as assigned by supervisor or QA. No more than 1 incidence of not completing QMS or lab section training requirements. <em>Proactively seeks one technical training opportunities from the following</em> - vendor classes or webinars association, government or other sponsor classes - online training - reads a book - reads 2 or more articles = 1 training [all above options must be approved by Supervisor] After training is completed, must submit a brief report describing the take-away points to supervisor</td>
</tr>
<tr>
<td>KRR</td>
<td>Training (continued)</td>
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</table>
| O   | 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. No incidences of not completing QMS or lab section training requirements.  
*Proactively seeks two technical training opportunities from the following*
  - vendor classes or webinars
  - association, government or other sponsor classes
  - online training
  - reads a book
  - reads 2 or more articles = 1 training
[all above options must be approved by Supervisor]
After training is completed, must submit a brief report describing the take-away points to supervisor.