ISO 17025:2005 on Reporting:

Section 5.10 with guest appearances from 4.4, 4.5, 4.7 & 4.8

Jason S. Kong
Ohio Department of Agriculture
Reynoldsburg, OH

2015 AAFCO Midyear Meeting
January 11 - 15, 2015
What does the standard say?

5.10.1 provides basic guidance for reporting values:

“Results of each test ... reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

“... shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results ... 

“... for internal customers ... or ... a written agreement with the customer ... the results may be reported in a simplified way.
5.10.1 - Your Customer

“Use your customer agreement to make the report as simple as possible.

“Information is still necessary, but not required for reporting.

“Section 4.4 should clarify reporting beforehand

“Measurement Uncertainty?

“Reports with subcontractors?
## FEED SAMPLE ANALYSIS REPORT

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Minimum Guarantee</th>
<th>Maximum Guarantee</th>
<th>Other Guarantee</th>
<th>Amount Found</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crude Protein</td>
<td></td>
<td></td>
<td>11.4 %</td>
<td>12.3 %</td>
<td>AAFCO 002.01</td>
</tr>
<tr>
<td>Crude Fat</td>
<td></td>
<td></td>
<td>3.26 %</td>
<td>2.9 %</td>
<td>AAFCO 003.13</td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
<td>0.65 %</td>
<td>0.73 %</td>
<td>AAFCO 019.43</td>
</tr>
<tr>
<td>Crude Fiber</td>
<td></td>
<td></td>
<td>2.67 %</td>
<td>2.5 %</td>
<td>AAFCO 004.07</td>
</tr>
<tr>
<td>Phosphorus</td>
<td></td>
<td></td>
<td>0.54 %</td>
<td>0.60 %</td>
<td>AAFCO 031.43</td>
</tr>
<tr>
<td>Selenium</td>
<td></td>
<td></td>
<td>0.29 ppm</td>
<td>0.40 ppm</td>
<td>AAFCO 034.53</td>
</tr>
</tbody>
</table>

Report ID: 401326

Report Printed: 12/18/2014
Sample Date: 1/30/2014
Laboratory ID: [Redacted]

AAFCO
Association of American Feed Control Officials
Sample Report Bottom

Clearly delineates total pages in report
5.10.2 – Minimum Reporting

- Title
- Name, Address of Lab
- Test Report Unique ID
- Reporting “completeness”
- Customer name, address
- Method used
- Sample condition
- Date of receipt of sample
- Date of test performed
- Reference to sampling plan
- Results
- Authorizing Identification
- And more!
5.10.2 – Minimum Reporting

“e) Methods require identification of revision date.

“When the date is not identified in the scope of accreditation, laboratories are expected to be competent in the use of the current version within one year of the date of publication of the standard...method.” – R101 from A2LA

“f) Descriptions of items can be a simple “acceptable” condition unless required to go into detail per 5.10.5 Opinions and Interpretations.
5.10.2 – Minimum Reporting

j) Electronic / mechanized signatures acceptable if protected from unauthorized use and is identifiable. The signature can be anything, as long as it is traceable!

- Social Security Number? (555-31-7834?)
- Random Configuration of Values? (EXKSFI205?)
- Code Words? (Red Falcon)

YES!!!
5.10.2 – Minimum Reporting

“k) Where relevant, a statement to the effect that the results relate only to the items tested or calibrated.”

<table>
<thead>
<tr>
<th>Program:</th>
<th>FEED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Plan:</td>
<td>2014_15D - Monitoring Inspection - Imported Corn</td>
</tr>
<tr>
<td>Sampling Method:</td>
<td>Stream sample</td>
</tr>
<tr>
<td>Inspector Sample No.:</td>
<td>14-4-10-</td>
</tr>
<tr>
<td>Sampling Type:</td>
<td>Primary Manufacturer, Producer</td>
</tr>
<tr>
<td>Country - Origin:</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Lot:</td>
<td>RAIL CAR:</td>
</tr>
<tr>
<td>Unit Volume/Weight:</td>
<td>1 ton_met</td>
</tr>
<tr>
<td>Container Type:</td>
<td>no packaging/bulk</td>
</tr>
<tr>
<td>Common Name:</td>
<td>YELLOW CORN</td>
</tr>
<tr>
<td>Product Regist. Code:</td>
<td>99INGRP</td>
</tr>
<tr>
<td>Total Weight (kg):</td>
<td>93 TONNE</td>
</tr>
<tr>
<td>Units on Hand:</td>
<td>93</td>
</tr>
<tr>
<td>Physical Form:</td>
<td>other</td>
</tr>
<tr>
<td>Invoice or Product ID:</td>
<td>RAIL CAR:</td>
</tr>
<tr>
<td>Bill of Lading:</td>
<td>APR 4/14</td>
</tr>
<tr>
<td>Method:</td>
<td>FD-TOXINS-MULTITOX</td>
</tr>
<tr>
<td></td>
<td>MULTITOX8</td>
</tr>
<tr>
<td>Aflatoxin B1 Result:</td>
<td>&lt;1.0 ug/kg</td>
</tr>
<tr>
<td>Aflatoxin B2 Result:</td>
<td>&lt;1.0 ug/kg</td>
</tr>
<tr>
<td>Aflatoxin G1 Resultat:</td>
<td>&lt;1.0 ug/kg</td>
</tr>
<tr>
<td>Aflatoxin G2 Resultat:</td>
<td>&lt;1.0 ug/kg</td>
</tr>
<tr>
<td>Total Aflatoxins Result:</td>
<td>&lt;5.0 ug/kg</td>
</tr>
<tr>
<td>Ochratoxin Result:</td>
<td>&lt;10 ug/kg</td>
</tr>
<tr>
<td>Zeaalenone Result:</td>
<td>&lt;100 ug/kg</td>
</tr>
<tr>
<td>HT-2 Result:</td>
<td>&lt;15 ug/kg</td>
</tr>
<tr>
<td>T-2 Result:</td>
<td>&lt;10 ug/kg</td>
</tr>
<tr>
<td>Date Authorized:</td>
<td>2014-05-28</td>
</tr>
<tr>
<td>Authorized By:</td>
<td>FRED ARMSTRONG</td>
</tr>
</tbody>
</table>

These results relate only to the sample as tested by this laboratory.

*** END OF REPORT ***
5.10.3 – “where necessary”

Method-specific requirements

5.10.3.2 Sampling Methods

Qualitative / Interpretive Results

LOD / LOQ Reporting

Program-specific requirements

Pesticide Data Program

Ohio Racing Commission
5.10.4 – Does This Apply?

“YES! Reporting is not just for outgoing reports from you, but for reports coming in to you, especially calibration reports!

“Protecting your ISO 17025 Accreditation by scrutinizing calibration reports performed for you

“ODA's experience with calibration reports for positive displacement pipette calibrations
CALIBRATION CERTIFICATE
Report Number: 1704458-1152014-15:00:00

Instrument Information
Serial # 1704458
Mfg. Type, and Size: Eppendorf Reference 100 variable, 100ul, 1ch
Customer: [Redacted]
Contact: [Redacted]
Department: [Redacted]
Address: [Redacted]
Device ID: 1704458

Environmental Factors
Temperature: 75.84 °F
Barometric pressure: 30.22 inHg
Relative humidity: 32.22 %
Liquid density: 0.9972
Z Factor: 1.0034188
Air density: 0.0011987
Cubic expansion: 0.0001000

Test Criteria
Test plan: CTL 100 ul 2 volume
Method: Level 6 - SOP125-6 4 AF 4 AL

Measurement & Test Equipment
Name: Balance - 23207324 - Sartorius - CP225D
Hygrometer - 122497029 - Control Company
Weight Set - 1DH6 - Rice Lake
Serial Number: 23207324
122497029
1DH6
Next Calibration Due: 31-Jan-2015
28-Feb-2015
30-Apr-2015

Parts, Repairs, & Restrictions
Adjust Calibration
Battery
ISO 17025
O-ring
Piston
Preventive Maint.
Routine Maint.
Seal
Shaft
Tension Ring
Notes

Statistics & Sample Data
<table>
<thead>
<tr>
<th>Ch</th>
<th>Target (µl)</th>
<th>Tolerances (+/µl)</th>
<th>Mean (µl)</th>
<th>Inaccuracy % Limit % Actual %</th>
<th>Imprecision % Limit % Actual %</th>
<th>Process Uncert. (+/µl)</th>
<th>Uncert. Guardband Tol. (+/µl)</th>
<th>Within k=2 95 % confidence</th>
<th>Status</th>
<th>Sample Weight (g)</th>
<th>Sample Volume (µl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25.00</td>
<td>0.75</td>
<td>25.16</td>
<td>3.00</td>
<td>0.65</td>
<td>3.00</td>
<td>0.13</td>
<td>0.03</td>
<td>Pass</td>
<td>0.02505</td>
<td>25.13564</td>
</tr>
<tr>
<td>2</td>
<td>25.00</td>
<td>0.75</td>
<td>25.16</td>
<td>3.00</td>
<td>0.65</td>
<td>3.00</td>
<td>0.13</td>
<td>0.03</td>
<td>Pass</td>
<td>0.02510</td>
<td>25.18581</td>
</tr>
<tr>
<td>3</td>
<td>100.00</td>
<td>3.00</td>
<td>100.49</td>
<td>3.00</td>
<td>0.49</td>
<td>3.00</td>
<td>0.11</td>
<td>0.11</td>
<td>Yes</td>
<td>0.02511</td>
<td>100.19566</td>
</tr>
<tr>
<td>4</td>
<td>100.00</td>
<td>3.00</td>
<td>100.49</td>
<td>3.00</td>
<td>0.49</td>
<td>3.00</td>
<td>0.11</td>
<td>0.11</td>
<td>Yes</td>
<td>0.02505</td>
<td>25.13564</td>
</tr>
</tbody>
</table>
5.10.4.4 A calibration certificate ... shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.
5.10.5 Opinions & Interpretations

Not to be confused with tests requiring qualitative RESULTS (e.g. feed microscopy / filth)

Opinions and Interpretations are strictly controlled if they are included in the report itself.

Opinions and interpretations may be given informally through e-mail, non-reporting letters, and according to NOTE 3, should be documented.
5.10.5 Opinions & Interpretations

In order for a report with opinions and interpretations to be included in an accredited report, the manner of how opinions and interpretations are given must be contained in a written procedure also within the lab’s scope of accreditation.
5.10.6 - Subcontractors

"Customer --> Laboratory --> Subcontracting Lab

"Results reported by subcontracting laboratories shall be recorded in writing or electronically by the laboratory

"Must be clearly identified for the customer to see
5.10.7 – Electronic Reports

“Should meet requirements of 5.4.7 Control of Data

“Reporting can be simplified according to a contract, memorandum of understanding, or similar document,

“(e.g. automatic database dumping into agency's electronic database)
5.10.8 – Reporting Formats

“NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

“NOTE 2 The headings should be standardized as far as possible.
# General Chemistry Analysis Report

**Customer Name:**

**Sample Type:** FEED

**Product Name:** RANGE & BREEDER CUBES

<table>
<thead>
<tr>
<th>Test</th>
<th>Guarantee</th>
<th>Test Result</th>
<th>Exceeds AV</th>
<th>Analysis Method</th>
<th>Analysis Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein, Crude</td>
<td>20.0 %</td>
<td>21.2 %</td>
<td></td>
<td>AOAC 990.03</td>
<td>9/11/2014</td>
</tr>
<tr>
<td>Fat, Crude</td>
<td>2.50 %</td>
<td>3.62 %</td>
<td></td>
<td>AOAC 920.39</td>
<td>9/18/2014</td>
</tr>
<tr>
<td>Fiber, Crude</td>
<td>9.00 %</td>
<td>10.8 %</td>
<td>Yes</td>
<td>Ankom Crude Fiber</td>
<td>9/25/2014</td>
</tr>
<tr>
<td>Salt (from Chloride)</td>
<td>0.75 - 1.25 %</td>
<td>1.07 %</td>
<td></td>
<td>AOAC 976.18</td>
<td>9/17/2014</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>10000 IU/lb</td>
<td>11300 IU/lb</td>
<td></td>
<td>AOAC 974.29</td>
<td>9/15/2014</td>
</tr>
<tr>
<td>Calcium</td>
<td>0.30 - 0.80 %</td>
<td>0.69 %</td>
<td></td>
<td>AOAC 2006.03</td>
<td>9/15/2014</td>
</tr>
<tr>
<td>Potassium</td>
<td>1.20 %</td>
<td>1.31 %</td>
<td></td>
<td>AOAC 2006.03</td>
<td>9/15/2014</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>0.75 %</td>
<td>0.85 %</td>
<td></td>
<td>AOAC 2006.03</td>
<td>9/15/2014</td>
</tr>
</tbody>
</table>

**Date Sampled:** 9/3/2014

**Date Received:** 9/8/2014

**Date Completed:** 9/25/2014

**Approved by:**

---

Department of Agriculture, Food, and Forestry

PO Box 528804
2800 N. Lincoln Blvd.
Oklahoma City, OK 73152-5431
Phone: (405) 522-5431
Fax: (405) 522-1853
5.10.9 – Amendments

Differentiating between an amendment (also a re-issue) and a new report

- Typos? Mistakes? Complaints?
- Request from customer to retest a sample?
- Reissuing a Report?
### 5.10.9 – Reissuing a Report

#### FEED SAMPLE ANALYSIS REPORT

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Minimum Guarantee</th>
<th>Maximum Guarantee</th>
<th>Other Guarantee</th>
<th>Amount Found</th>
<th>Method</th>
<th>Result Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium</td>
<td>33 %</td>
<td>38 %</td>
<td>8000 g/ton</td>
<td>0.20 ppm</td>
<td>AAFCO 518.52</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
<td></td>
<td>34.2 %</td>
<td>AAFCO 019.42</td>
<td></td>
</tr>
<tr>
<td>Cobalt</td>
<td></td>
<td></td>
<td></td>
<td>6.13 ppm</td>
<td>AAFCO 025.52</td>
<td></td>
</tr>
<tr>
<td>Lead</td>
<td></td>
<td></td>
<td></td>
<td>1.37 ppm</td>
<td>AAFCO 526.52</td>
<td></td>
</tr>
<tr>
<td>Mercury</td>
<td></td>
<td></td>
<td></td>
<td>&lt; 20 ppb</td>
<td>AAFCO 529.99</td>
<td></td>
</tr>
<tr>
<td>Molybdenum</td>
<td></td>
<td></td>
<td></td>
<td>0.68 ppm</td>
<td>AAFCO 038.52</td>
<td></td>
</tr>
<tr>
<td>Monensin</td>
<td></td>
<td></td>
<td></td>
<td>7910 g/ton</td>
<td>AAFCO 065.99</td>
<td></td>
</tr>
<tr>
<td>Selenium</td>
<td></td>
<td></td>
<td></td>
<td>1.42 ppm</td>
<td>AAFCO 034.52</td>
<td></td>
</tr>
</tbody>
</table>
4.7.2 - Feedback

Use your customer review to provide feedback on reporting and how it can be improved.

Example – Annual Customer Review from internal customers provide opportunities to improve reporting methods, especially when issues have been documented in the past.
AOAC Additional Guidance

“Procedures shall be established to prevent the production of unauthorized reports and other documents."
4.8 Requests for Splits and Referee Laboratories

This section can be clarified in reporting, re-issuing reports and such if properly documented in contracts and/or MOUs.
A2LA Additional Guidance

"Logos of “A2LA Accredited,” “ILAC MRA” or equivalent are not required except for calibration laboratories. Logos have a policy for use; consult your accrediting body for details.

For A2LA, consult document R105 – Requirements When Making Reference to A2LA Accredited Status"
What if the reporting scheme is:

Laboratory -> Internal Customer -> Customer?

My laboratory is internal to a larger, manufacturing organization. Test results are communicated from the laboratory via an intranet to another department of the organization which prepares and issues the final test reports, but they may or may not contain all of the elements of Section 5.10.2 through 5.10.4. Can a deficiency be cited against our laboratory for non-compliance with these clauses of ISO/IEC 17025?
In the case of captive or internal laboratories, the “customer” is most often considered to be another department within the larger, overall organization. As long as there is a documented understanding from that other department within the organization as to the format that the final report issued by the captive laboratory will take, then the laboratory is free to issue a simplified report under the provisions of Section 5.10.1. According to these provisions, the laboratory may issue a report to their “customer” within the organization such that not all elements of 5.10.2 through 5.10.4 need be included, as long as the results are reported accurately, clearly, unambiguously and objectively. However, the lab itself must maintain records to satisfy the elements of 5.10.2 through 5.10.4 in the event that information is ever needed.

Now, if the other department within the organization wishes to distribute the captive laboratory’s results to someone outside the organization, they may do so. The results are only considered “accredited”, however, if the laboratory’s actual report is given to this outside party. In other words, the other department within the organization may not repackage, manipulate or re-present the laboratory’s data in another form before it is distributed to this external party and still have it considered “accredited” or have it display the “A2LA Accredited” symbol (or reference to A2LA accreditation). If the other department re-packages, manipulates or re-presents the data and still makes reference to A2LA accreditation in its issued report, we would consider this department of the organization (not the laboratory itself) to be issuing a fraudulent report, and would take necessary action.
Basically, your original report is the accredited report and may have the accreditation logo.

Any modification or repackaging of the report by the internal customer negates the ability to attach the accreditation logo.