ISO 17025:2005 on Reporting:

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

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2015 AAFCO Midyear Meeting
January 11 - 15, 2015

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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.

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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?

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Sample Report Top

[redacted]

[redacted]

Report Printed: 12/18/2014

Sample Date: 1/30/2014

Laboratory ID: [redacted]

Report ID: 401326

FEED SAMPLE ANALYSIS REPORT

Inspector ID: [redacted]

Inspector Name: [redacted]

Product Name: [redacted]

Analyte	Minimum Guarantee	Maximum Guarantee	Other Guarantee	Amount Found	Method	Result	nts
Crude Protein			11.4 %	12.3 %	AAFCO 002.01		
Crude Fat			3.26 %	2.9 %	AAFCO 003.13		
Calcium			0.65 %	0.73 %	AAFCO 019.43		
Crude Fiber			2.67 %	2.5 %	AAFCO 004.07		
Phosphorus			0.54 %	0.60 %	AAFCO 031.43		
Selenium			0.29 ppm	0.40 ppm	AAFCO 034.53		

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Sample Report Bottom

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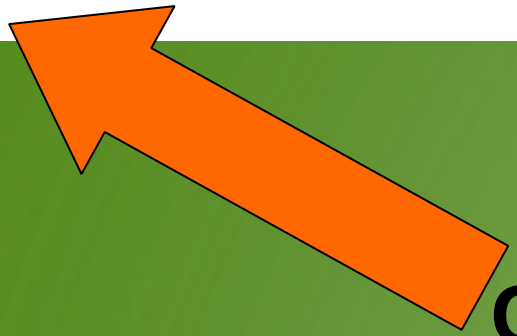
Laboratory Supervisor Date



Clearly delineates total pages in report

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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.

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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!

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5.10.2 – Minimum Reporting

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

Program: FEED	***Project:*** Biological Contaminants		***Function:*** IMPORT
Sample Plan:	2014_15D - Monitoring Inspection - Imported Corn	***Sample Priority:*** Regular	
Sampling Method:	Stream sample		
Inspector Sample No.:	**14-4-10-**		
Sampling Type:	Primary Manufacturer, Producer	***Common Name:***	YELLOW CORN
Country - Origin:	UNITED STATES	***Product Regist. Code:***	99INGRP
Lot:	RAIL CAR:	***Total Weight (kg):***	93 TONNE
Unit Volume/Weight:	1 ton_met	***Units on Hand:***	93
Container Type:	no packaging/bulk	***Physical Form:***	other
		Invoice or Product ID:	RAIL CAR:
		Bill of Lading:	APR 4/14

Method:	FD-TOXINS-MULTITOX	MULTITOX8
	Aflatoxin B1 Result	<1.0 ug/kg
	Aflatoxin B2 Result	<1.0 ug/kg
	Aflatoxin G1 Resultat	<1.0 ug/kg
	Aflatoxin G2 Resultat	<1.0 ug/kg
	Total Aflatoxins Result	<5.0 ug/kg
	Ochratoxin Result	<10 ug/kg
	Zearalenone Result	<100 ug/kg
	HT-2 Result	<15 ug/kg
	T-2 Result	<10 ug/kg

Date Authorized: 2014-05-28 ***Authorized By:*** FRED ARMSTRONG

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

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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

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[redacted]

CALIBRATION CERTIFICATE

Report Number: 1704458-1152014-15:00:00

[redacted]

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Serial # 1704458

Data type: As Found
SOP followed: Level 6 - SOP125-6
Calibration date: 05-Nov-2014

Status: Passed
Work order # BJ14110501

Instrument Information

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

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

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.

Next Calibration Due

31-Jan-2015
28-Feb-2015
30-Apr-2015

Notes

- ☐ cGMP
- ☐ Non-Routine Maint.
- ☐ Repair
- ☐ Tension Ring
- ☐ Routine Maint.
- ☐ Seal
- ☐ Shaft

Statistics & Sample Data

Ch	Target (µl)	Tolerances (+/- µl)	Mean (µl)	Inaccuracy % Limit %	Inaccuracy % Actual %	Imprecision % Limit %	Imprecision % Actual %	Process Uncert. (+/-µl)	Uncert. Guardband Tol. (+/-µl)	Within k=2 95 % confidence	Status	Sample	Sample Weight (g)	Sample Volume (µl)
1	25.00	0.75	25.16	3.00	0.65	3.00	0.13	0.03	0.72	Yes	Pass			
												1	0.02505	25.13564
												2	0.02510	25.18581
												3	0.02511	25.19585
												4	0.02505	25.13564
1	100.00	3.00	100.49	3.00	0.49	3.00	0.11	0.11	2.89	Yes	Pass			

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.

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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

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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)

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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.

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5.10.8 – Reporting Formats

Oklahoma Department of Agriculture, Food, and Forestry

PO Box 528804
2800 N. Lincoln Blvd.
Oklahoma City, OK 73152-5431
Phone: (405) 522-5431
Fax: (405) 522-1855

General Chemistry Analysis Report

Customer Name [redacted]
[redacted]
OKLAHOMA CITY, OK[redacted]

Sample Type FEED
Product Name [redacted] RANGE & BREEDER CUBES[redacted]
Guarantor [redacted]

Lab Number GC150[redacted]1
Customer Number 15-[redacted]

Date Sampled 9/3/2014
Date Received 9/8/2014
Date Completed 9/25/2014

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

[redacted]
Approved by [redacted]

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?

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5.10.9 – Reissuing a Report

[redacted]

[redacted]

Report Printed: 12/18/2014

Sample Date: 8/6/2014

Laboratory ID: [redacted]

Re-issue of Report ID: 413718

FEED SAMPLE ANALYSIS REPORT

Inspector ID: [redacted]

Inspector Name: [redacted]

Product Name: [redacted]

Analyte	Minimum Guarantee	Maximum Guarantee	Other Guarantee	Amount Found	Method	Result Comments
Cadmium				0.20 ppm	AAFCO 518.52	
Calcium	33 %	38 %		34.2 %	AAFCO 019.42	
Cobalt				6.13 ppm	AAFCO 025.52	
Lead				1.37 ppm	AAFCO 526.52	
Mercury				< 20 ppb	AAFCO 529.99	
Molybdenum				0.68 ppm	AAFCO 038.52	
Monensin			8000 g/ton	7910 g/ton	AAFCO 065.99	
Selenium				1.42 ppm	AAFCO 034.52	

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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.

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AOAC Additional Guidance

“Procedures shall be established to prevent the production of unauthorized reports and other documents.

AAFCO Additional Guidance

- 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.

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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

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A2LA Additional Guidance

"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?

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A2LA Additional Guidance

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.

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A2LA Additional Guidance

"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.**

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