

QMS Quick Learning Activity

Data Review and Reporting in ISO/IEC 17025:2005

Section 5.10 with guest
appearances from 4.7.2 & 5.4.7

What does the standard say?

5.10.1 - basic guidance for reporting values

- Results of each test shall be reported
 - accurately
 - clearly
 - unambiguously and objectively
 - in accordance with any specific instructions in the test or calibration methods.
- Reports shall include
 - all the information requested by the customer
 - necessary for the interpretation of the test or calibration results.
- Internal customers (or when there is a written agreement with customer) results may be reported in a simplified way.



5.10.1 - Your Customer

- Customer agreements can be used to make the report as simple as possible.
- Information may be necessary, but not required for reporting.
- Section 4.4 (Review of Requests, Tenders, and Contracts) clarifies reporting beforehand
 - Measurement Uncertainty
 - Reports with subcontractors



5.10.2 Reporting Requirements

Customer name/address ABC Feed Corporation 123 Main Street Hometown, OK 12345		Name/Address of Lab Feed First Laboratory 126 Animal Way Best Friend City, Oklahoma, NB 12345		Report Printed: 12/18/2014 Sample Date: 1/30/2014 Laboratory ID: 16C01235	
Report ID: 401326		FEED SAMPLE ANALYSIS REPORT			
Inspector ID: 456	Inspector Name: D. Martyn		Product Name: ACE Rabbit Feed		
Analyte	Minimum Guarantee	Other Guarantee	Amount Found	Method	Result Comments
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	



Reporting Requirements

Page 1 of 1

Laboratory Supervisor

Date



5.10.2 – Minimum Reporting

- e) Methods require identification.
- f) Descriptions of items can be a simple
 - “acceptable” condition unless required to go into detail per 5.10.5, Opinions and Interpretations.
- j) Electronic / mechanized signatures are acceptable if protected from unauthorized use and is identifiable. The signature must be traceable!
 - There is no specified format.



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”

- for the interpretation of test results
 - Deviations, additions or exclusions from test method
 - Information of specific test conditions (environmental conditions)
 - Statement on compliance/non-compliance with requirements and/or specifications
 - Statement on estimated uncertainty
 - Opinions and Interpretations
 - Program-specific requirements



5.10.3 – “where necessary” -sampling

- for the interpretation of test results for reports containing results of sampling
 - Date of sampling
 - Unambiguous identification
 - Location of sampling
 - Reference to sampling plan
 - Environmental conditions that may effect interpretation
 - Sampling method and/or deviations/additions or exclusions



5.10.4 – Calibration certificates

Does this section apply to our Laboratory?

- YES! Reporting is not just for outgoing reports from us, but for reports coming in, especially calibration reports!
- Important step in protecting ISO/IEC 17025 Accreditation is to scrutinizing calibration reports for calibrations performed for us.
 - Calibration reports need have required information. Our laboratory is customer for the calibration laboratories!



CALIBRATION CERTIFICATE

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

Serial # 1704458

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

Status: Passed
Work order # BJ14110501

Page 1 of 1

Instrument Information

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

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

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	1	0.10004	100.05004

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 of ISO/IEC 17025, 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 basis of how opinions and interpretations have been made must be documented.
- Opinions clearly marked as such on test report.



5.10.6 - Subcontractors

Customer --> Laboratory --> Subcontracting

- Results reported by subcontracting laboratories shall be recorded in writing or electronically by the laboratory
- Must be clearly identified as coming from the subcontractor laboratory for the customer to see



5.10.7 – Electronic Reports

- Should meet requirements of section 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

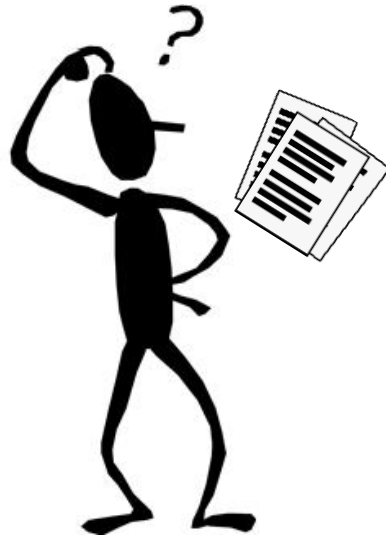


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5.10.8 – Reporting Formats

Reports formatted in a way to minimize the possibility of misunderstanding or misuse.



5.10.8 – Reporting Formats

Oklahoma Department of Agriculture, Food, and Forestry

General Chemistry Analysis Report

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

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]



QMS Quick Learning Activity

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 – Amendments

- Amendments made only in the form of a further document, or data transfer
- Includes a statement similar to:
“Supplement to Test Report, serial number (or otherwise identified)”
- Amendments meet all of the reporting requirements



5.10.9 – Amendments

- If new test reports need to be issued, they shall
 - Be uniquely identified
 - Contain reference to original report



4.7.2 - Feedback

- Customer can provide feedback on reporting and how it can be improved.



Data Review – section 5.4.7

- Calculations/data transfers subject to checks in a systematic manner.
- Quality management system procedures document how this is done

REVIEW



Records of reviews

4.13.2.1

- The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and *checking of results*.



In Conclusion: Reporting

- ISO/IEC 17025 has specific requirements for generating reports
 - Objective
 - Meets needs of customer
 - Includes additional information required needed for interpretation of results
 - Easy to understand/follow
- Reports may be simplified if reporting to an internal customer or if there is an written agreement with customer in place.



References

ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

- <https://www.iso.org/standard/39883.html>

