AUDITING GAS LABORITORIES

Class 5010
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Why **Should** We Audit?

The data produced by Gas Chromatograph (GC) laboratories is used for many purposes, including product specification, accounting, safety and environmental compliance issues. The accuracy of this data has direct impact on all of these areas. Auditing laboratories responsible for producing this data is prudent business practice. The audit will provide a means of process improvement, through proper identification of deficiencies and a precise plan for corrective action. The level of confidence in analytical results will increase when the appropriate corrective actions are implemented. The amount of financial and legal exposure can be reduced from a properly executed audit program.

When Should We Audit?

Audits should be performed on a scheduled frequency, typically once a year for laboratories, and quarterly or semi-annually for online analyzers. If a discrepancy arises, or there is concern about the accuracy of analytical data, an audit should be performed. If there has been a change in personnel or equipment an audit may be warranted. After corrective action has been taken, an audit may be performed to determine the level of improvement.

What Should We Audit?

Many audits are performance evaluations that can disrupt the routine procedures of the laboratory being audited. That is, the sample container is not remotely similar to sample containers routinely handled by the laboratory. As a result, the day-to-day sample handling process is not followed explicitly. The data is not handled in the same manner as normal workload samples. The laboratory technicians' daily routine is disrupted. These audit results demonstrate how the lab can perform when required to modify its process to accommodate the audit sample and auditor, but fail to accomplish the real objectives of the audit.

The ideal audit will examine the entire process from receipt of samples to reporting and cylinder cleaning. Not only does the performance need to be evaluated, but also the entire analytical process. Policies and procedures should be scrutinized to confirm contractual compliance and good laboratory practices are in place. Review of documentation such as Standard Operating Procedures (SOP's), Quality Assurance/Quality Control (QA/QC) manuals, industry standards manuals and maintenance and QA/QC records will give insight into the laboratories commitment to produce accurate data.

How Do We Conduct An Audit?

The audit should be scheduled and performed when the laboratory can accommodate the audit. Laboratory workloads tend to be heaviest at the beginning and end of each month. It is normally easiest to schedule the audit in the middle of the month. It is common courtesy to send a letter of request to the party being audited. A confidentiality agreement is normally included to prevent unauthorized distribution of the audit findings. This serves as an introduction from the auditor, and helps bring harmony to the effort. Also, the request should include documentation required by the auditor, such as SOP's, QA manuals, and maintenance records. In the case of a double-blind PE sample, the letter may come after the PE sample has been analyzed by the laboratory, but prior to the auditor's visitation.

Before we can construct an effective audit program, we must establish what means will be used to conduct the audit. Every effort should be made to evaluate the laboratory performance under real-world conditions. There are two types of Performance Evaluation samples used for auditing: Blind Samples and Double-Blind Samples. The Blind Sample is a sample of known composition that is delivered to the laboratory as an "audit" sample, normally at the time of the auditor's visit. This type of audit sample is normally in a bulky container similar to the lab's calibration blends. The Double-Blind Sample is a sample of known composition that is delivered to the laboratory and is not declared to be an audit sample. This type of audit sample is normally in a container similar to sample containers normally handled by the lab for analysis. The laboratory handles and analyzes this sample as it would any production sample and is unaware that it is a PE sample. This will provide the most accurate determination of laboratory performance under normal conditions. The auditor will visit the laboratory after receiving the report to collect and review pertinent data and processes.

In most cases, more than one PE sample should be used to cover the range of samples analyzed by the laboratory. This will uncover potential problems caused by nonlinearity, or procedures within the laboratory that fail to correct for nonlinearity.

Regardless of the PE sample used, the auditor should review contracts, QA manuals, and SOP's during the course of the audit. During the laboratory visitation maintenance records, calibration records, calibration blend certifications, raw data, and QA records should be reviewed. A process review should be performed, tracing the sample from receipt, through login, sample handling, analysis, calculations, reporting and cylinder cleaning. Review the instrument configuration, including carrier gases, filters, sample lines, ovens and heated zones, valves and plumbing, columns, detectors and data systems.

Brief, well-constructed interviews of laboratory personnel involved in all portions of the process will improve the auditor's understanding of the process and may reveal compliance issues. The auditor should develop the interview from the review of SOP's and applicable test methods performed for the audit.

How Do We Evaluate Laboratory Performance?

Laboratory performance is normally evaluated by comparing the results of a PE sample to the certified composition of the PE sample. The method used for analyzing the sample will typically have a section that states the expected precision of the method. Unless the contract governing the analysis specifies another means of evaluating the laboratory performance, the method's precision statement should be adhered to, including the stated concentration range for the level of precision.
Also, the laboratory personnel should follow their SOP's. The evaluation must also determine whether personnel take the steps necessary to provide analytical quality.

How Do We Report Audit Findings?

The audit report must be accurate and properly address issues that require corrective action. The performance of the laboratory should be included in the Final Audit Report. Sometimes these findings will be displayed both in a tabular and graphical format.
Other issues that may have a potential impact on accuracy should be included in the report. These include process, documentation, and training. The SOP's, QA/QC manual, industry standards, and contract should be referenced where applicable. The potential impact on accuracy should be noted. The recommended corrective action must also be documented. This section should be in summary form, with backup documentation available.

What Are Typical Audit Findings?

Audit findings fall into several categories; Process, Performance, and Personnel. Each of these will have an impact on overall quality.

Typical process problems are inadequate procedures, or failure to properly implement those described in the SOP's. This is why review of laboratory SOP's and manuals is important. The documentation lists how the process should work, and sometimes steps in the process are either missing or not clear.

Performance issues typically relate to faulty equipment, calibration blends or analytical technique. The audit should clearly identify the cause(s). The results of the PE sample should demonstrate both repeatability and reproducibility. Repeatability is the precision demonstrated when the same person performs an analysis of the same sample on the same instrument. Reproducibility is the ability of different technicians, using different instruments to obtain similar results. Reproducibility is often expressed as the difference between the laboratory's results and the known composition of the PE sample. It is beneficial to determine the lab's internal reproducibility by comparing the results from the same sample analyzed by different technicians on different instruments in the same laboratory.

The personnel interviews may show training deficiencies. It is not uncommon to find that personnel do not fully understand and follow SOP's as they were intended. Lack of proper training offers a high probability of increased analytical uncertainty. The review should avoid singling out individuals while focusing on processes.

AUDIT DATA

PERFORMED FOR:	Client										DATE PERFORMED:		5/12/2009			
			LEAN GAS - UNKNOWN								TECHNICIAN:		Billy Bob			
COMPANY:	ABC Corp.			Inst. No. :	GC1											
LOCATION:	Central Texas			Manufacturer :	Chromowhiz						GC SERIAL NO:		ABC123			
METHOD :	GPA 2261															
	LEAN GAS TEST SAMPLE			TEST GAS 01							DATE:		1/9/2009			
COMPONENTS	CERT	MOL %	MOL %	AVG	REPEATABILITY SPECS.						REPRODUCIBILITY					
	MOL %	RUN 1	RUN 2	MOL %		GPA		API				GPA		API		
												X1	P/F	X1	P/F	
HYDROGEN	0.0000	0.0000	0.0000	0.0000												
HELIUM	0.0000	0.0000	0.0000	0.0000												
OXYGEN	0.0000	0.0000	0.0000	0.0000												
NITROGEN	4.9000	4.8800	4.9200	4.9000	0.82	2.0	P	0.10	P		0.41	7.0	P	0.130	P	
* METHANE	88.0000	87.9800	87.9200	87.9500	0.07	0.2	P	0.52	P		0.09	0.7	P	0.630	P	
CARBON DIOXIDE	2.8000	2.8500	2.8700	2.8600	0.70	3.0	P	0.10	P		2.50	12.0	P	0.130	P	
* ETHANE	1.9000	1.9100	1.8800	1.8950	1.58	1.0	F	0.10	P		1.05	2.0	P	0.130	P	
* PROPANE	1.0000	1.0100	0.9900	1.0000	2.00	1.0	F	0.02	P		1.00	2.0	P	0.040	P	
ISOBUTANE	0.4500	0.4700	0.4600	0.4650	2.15	2.0	P	0.02	P		4.44	4.0	F	0.040	P	
* N-BUTANE	0.4500	0.4500	0.4600	0.4550	2.20	2.0	P	0.02	P		2.22	4.0	P	0.040	P	
ISOPENTANE	0.2000	0.1900	0.2100	0.2000	10.03	3.0	F	0.02	P		5.00	6.0	P	0.040	P	
N-PENTANE	0.1500	0.1400	0.1300	0.1350	7.42	3.0	P	0.02	P		13.33	6.0	F	0.040	P	
HEXANES PLUS	0.1500	0.1200	0.1600	0.1400	29.17	10.0	F	0.02	F		20.00	30.0	P	0.040	P	
TOTALS	100.0000	100.0000	100.0000	100.0000												
BTU @ 14.696	1088.0	1082.0	1085.0	**REMARKS:**												
Relative Density (Real) =	0.6550			* = Componet outside of GPA repeatability and reproducibility study range.												
ABC Corp. BTU DRY =		1081.0	1084.0													
BTU Difference from actual =		7.0	4.0													
BTU Precision =		2.1213														
ABC Corp. RELATIVE DENSITY =		0.6530	0.6520													
Relative Density Difference from actual =		0.0020	0.0030													
Relative Density Precision =		0.0007														

SPL Inc.
Natural Gas Analysis
Lab Review Checklist

Lab Number :	**SPL Inc**	**Date :**	**May 6, 2012**
Audit Team Members :	**(SPL INC.)**		
	0	**S/N**	**0**

Sample Handling & Conditioning	**YES**	**NO**	**N/A**
Are sample cylinders Heated ?			
If sample cylinders are heated, to what temperature ?			
Is the sample cylinder temperature monitored ?			
Is the sample heated for at least 2 hours ?			
Is the sample cylinder cleaned before each use ?			
Is the sample cylinder heating time monitored ?			
What is the length of time used for heating sample cylinders ? (# Hours)			
Are samples taken immediately from heater to analyzer if manually transferred ?			
What method is used to insulate heated sample cylinders during analysis ?			
Insulated blanket			
Heated cabinet			
Other (Specify in Comments)			

Physical Facility	**YES**	**NO**	**N/A**
Is the analyzer room heated ?			
is the analyzer room Air-conditioned ?			

Filters, Connections and Hardware	**YES**	**NO**	**N/A**
Are filters used between sample and analyzer ?			
Type :			
Size :			
Replacement Interval :			
What is the size, length and material of sample line and fittings ?			
Are connections, lines, and hardware between sample and analyzer insulated ?			
Are connections, lines, and hardware between sample and analyzer heated ?			
Sample loop size is : 0.25 cc			
0.50 cc			
1.00 cc			
Other (specify size example 100ul)			

Injection System	**YES**	**NO**	**N/A**
Is the sample system a Vacuum Injection System ?			
Is the sample system a Purge Injection System ?			
If Purge Injection System, is there back pressure ?			
Can the Purge rate be read or measured ?			
What is the Purge Rate ?			
What is the speed loop Rate (If applicable)?			

What Should the Results of the Audit Produce?

An audit that is properly designed and implemented will provide a vehicle for overall laboratory improvement. The relationship between auditor and audited will be strengthened. Process and performance improvement will result in lower analytical uncertainty. Lower analytical uncertainty will have a measurable impact on regulatory and financial issues.