

Case Study #1: The Strange Case of the Missing Ocular

While inspecting a microbiological laboratory, an assessor noted the presence of a single stereoscopic microscope with a missing ocular. Prior to the on-site assessment, the assessor reviewed the laboratory's SOP for Total Coliform Analysis. He knew the procedure called for the use of a stereoscopic microscope for counting coliform colonies. The assessor asked the analyst if she used the microscope for standard plate counts, and she responded in the affirmative. The laboratory logbook supported the analyst's statement that she had performed the standard plate counts.

Suspecting that the analyst had fabricated the data, the assessor compiled the objective evidence, and discussed the findings with laboratory management during the exit briefing. Laboratory management was able to produce records showing that they had rented a microscope to complete the plate counts, and returned the microscope the previous day. The analyst, due to cultural differences, unassertiveness or a communication barrier, was uncomfortable explaining that the laboratory did not have properly functioning equipment, but had used rented equipment.*

Study Questions:

1. What are the morals of this story?
2. What is the solution to this problem?
3. How could a Quality Management Plan helped in this instance?
4. What kind of preventative action could have helped to avoid this situation?
5. Describe the objective evidence that the assessor should have compiled.
6. What is the biggest risk in this situation?

* 1. Is my solution to the problem legal and moral?

2. Do I feel good about my decision?

3. If my actions were publicized on national news, could I live with the consequences?

Case Study #2: Easy Does it

While analyzing samples an ICP analyst noted that the method blank for one batch of samples contained concentrations of several target analytes at concentrations exceeding the reporting limit. The analyst rejected the data, and requested the re-preparation of the batch.

After the samples had been prepared again, the analyst noted that the all sample volumes were 90 mL; however, the method blank volume was 100mL. The analyst, suspecting a shortcut, reported the observation to the QA Manager.

The QA Manager interviewed the technician, who had been employed by the laboratory for 6 months. The technician had received sample preparation training and ethics training during his first month on the job. He also had 8 years of experience in environmental sampling and analysis. The technician admitted having simply transferred the original sample digestates into new containers and assigned a redigestion batch number. The new “method blank” was merely acidified, deionized water.

The technician admitted to the shortcut, but claimed it was the first time he had ever done anything improper.*

Study Questions:

1. What types of improper practices have occurred?
2. What specific red flag pointed to the problem?
3. What other red flags might have been apparent to either internal or third party assessors?
4. What are some laboratory quality system elements that can promote the early detection and correction of this type of improper practice?
5. What steps could an assessor (either internal or third party) take to make sure this is an isolated incident, and not an indicator of a more serious vulnerability?

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Case Study #3 – Assessor Clousseau

This is what happened:

According to the sampling and analysis plan, marine water microbiological samples to be analyzed for enterococci were to be kept cool under ice and reach the laboratory within 4 hours following collection. Analysis was to begin within 8 hours following collection. Samples were collected at 8:00 am, but because the sample custodian took an extended lunch that day, the samples could not be delivered until 2:00 pm. The custodian failed to note sample temperature upon receipt, the presence or absence of ice, or that the samples had been delivered outside of hold time.

The samples were analyzed for streptococci, but were reported as enterococci.*

Study Question:

1. You are a third party assessor, contracted to perform a compliance assessment for the project in question. You are to be commended for uncovering this debacle, but exactly how did you do it?
2. Where did you start?
3. Trace the trail and record what you would do.

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Case Study #4 – Dip and Swirl

An assessor evaluating randomly selected laboratory reports for the past year noticed a significant reduction in the number of base/neutral and acid-extractable samples requiring re-extraction because of low surrogate recoveries. No reason for the improvement was readily apparent, and the assessor pointed out the observation during the exit brief.

The QA Manager conducted an after-hours check of the GC/MS laboratory, and discovered a small, unmarked vial containing a glass rod, near one of the instruments. Analysis of the contents revealed the vial contained a low-level surrogate solution. Under surveillance the next day, the analyst was observed occasionally dipping the glass rod into the vial, and then into selected samples. In this manner, she was raising surrogate recoveries in those samples for which initial results were too low.*

Study Questions:

1. What other data assessment red flags might have been observed?
2. What Quality System vulnerabilities might exist?

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Case Study #5 – The Oil Slick

To support a high-visibility emergency response effort involving an oil spill adjacent to a drinking water reservoir, a laboratory was contracted to perform rapid turnaround analysis for total recoverable petroleum hydrocarbons using Infrared Spectroscopy. Results were being used to guide the soil removal, an around-the-clock operation, which had been going on for a week.

Results for samples delivered to the laboratory at 4:00 pm were to be reported by 8:00 pm. The on-duty analyst reported the sample results, all of which were non-detects, by 5:00 pm, just before the end of the first shift. At 5:00 pm, however, the second shift analyst noticed that the glassware dedicated for this project was in the oven, where it had been placed the night before. (The glassware cleaning SOP required a 2-hour glassware-baking period at 100 degrees C, following cleaning.) It would have been impossible to have performed the analysis, cleaned the glassware, and returned it to the oven in the hour between the time samples were received and results reported. The second shift analyst reported the observation to the QA Manager.

The next day following questioning, the first analyst, who had been employed at the lab for two years, admitted to fabricating the data. He had actually developed a strip chart recording showing the standards, quality control results and sample results.*

Study Questions:

1. What are some technical area red flags that could have been observed?
2. What are some data assessment red flags that could have been observed?
3. What quality system red flags could be apparent?
4. What should the QA Manager do first? Can this be handled internally?
5. What should be done to determine the impacts of this improper practice?
6. The QA Manager recommended that the analyst be retrained. Is this effective corrective action?

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Case Study #6 – Name that Tune

You are reviewing the data package for pre-assessment PT samples for volatile organics by SW-846 Method 8260, and you notice that the BFB Tune was performed 7 days after the PT sample was analyzed. During the on-site assessment, you bring this to the GC/MS supervisor's attention, and he explains the discrepancy as a computer glitch.*

Study Questions:

1. What should you do?
2. Assuming the audit trail confirms that the tune file has been overwritten, what should you do?
3. What would you expect to see in the laboratory's Corrective Action Plan?

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Case Study #7 – Time Warp

A large Architectural Engineering (AE) firm used its in-house laboratory to support Remedial Investigations (RI) and Feasibility Studies (FS) at several Superfund sites. The Statement of Work required 14-day hold times for the GC/MS analyses of ground water samples, and imposed significant financial penalties for failure to meet hold times. During an internal assessment, the QA Manager for the firm discovered that some employees had changed the date and time on the GC/MS clock, to make it appear samples had been analyzed within hold times, when they had not. The firm subsequently disclosed the problem to EPA, which triggered an investigation including paper assessments and electronic tape audits. The impacts of the practices included:

- § Invalidation of a portion of the data used in the RI/FS
- § Re-sampling and re-analysis of some ground water samples
- § Costs of the follow-up paper assessments and tape audits
- § Referral for criminal investigation, and
- § Delays in site closure

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Study Questions:

1. What system vulnerabilities could have alerted assessors to the potential for these practices?
2. What red flags might have been apparent if a project compliance assessment had been conducted during the course of the project?
3. What assessment tools would have been most effective in identifying the system vulnerabilities and red flags?

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Case Study #8 – Analysis Disclosure

The Humpty Dumpty Laboratory analyzes a drinking water sample upon the request of Mother Goose Realty Company. The drinking water sample is from a primary private well, located on a farm that is listed for sale by Mother Goose. Jack and Jill citizen, who are interested in purchasing the property, called Humpty Dumpty and requested the drinking water analysis data results.*

Study Questions:

1. Should Humpty Dumpty release the results of the analysis to Jack and Jill?
2. Considering public disclosure laws, should Humpty Dumpty call Mother Goose?
3. Should Mother Goose call Jack and Jill?
4. Is a public disclosure policy necessary?
5. If you receive this phone call what would you do?

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