



Ethics and Inappropriate Practices from a Data User Perspective

EMDQ Workshop

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Agenda

- Ethics and Inappropriate Practices
- QSM Requirements
- Case Studies: Old & New

Ethics

- What are Ethics, anyway?
 - Should your mother get the blame?
 - Can ethics be truly taught to someone?
 - Is “right” and “wrong” that distinguishable in a laboratory environment?

Inappropriate Practices

- If Ethics cannot be taught, what can be done?
 - Define practices that are not acceptable.
 - **Improper Actions**: **Intentional** or unintentional deviations from contract-specified or method-specified analytical practices that has not been **authorized** by the customer.

Inappropriate Practices

- What should the laboratory do to prevent inappropriate practices?
 - Rigorous training on preventing improper behavior.
 - Up to date and detailed Standard Operating Procedures (SOPs) that reflect actual work.
 - Rigorous internal audits.
 - Use of electronic mining tools on reportable data.
 - Thorough three-tiered data review.

QSM Requirements

- **QSM 4.2.8.1.c):** A documented **program** to detect and deter improper or unethical actions.
- What does this program consist of?
 - Ethics policy signed by all personnel.
 - Initial and annual Ethics training.
 - Analysts must record an explanation and sign off on all manual changes to data.
 - Enable all electronic tracking and audit functions.

QSM Requirements

- **TNI 5.2.7:** Data Integrity Training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees.
 - Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient.

QSM Requirements

QSM 5.2.7:

Top management acknowledges its support for data integrity by implementing the specific requirements of the laboratory's data integrity program.

QSM 5.2.7: Prohibited Practices

QSM 5.2.7 lists practices that are prohibited

➤ **QSM 5.2.7 a)**

Fabrication, falsification, or misrepresentation of data.

- i. Creating data for an analysis that was not performed.
- ii. Creating information for a sample that was not collected.
- iii. Using external analysts, equipment, or laboratories when not allowed by contract.

QSM 5.2.7: Prohibited Practices

➤ **QSM 5.2.7 b)**

Improper clock writing or improper data/time recording.

- i. Resetting the internal clock on an instrument to make it appear that a sample was analyzed within holding time when in fact it was not.
- ii. Changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions or other steps to make it appear that holding times were met.

QSM 5.2.7: Prohibited Practices

➤ **QSM 5.2.7 c)**

Unwarranted manipulation of samples, software, or analytical conditions.

- i. Unjustified dilution of samples.
- ii. Manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria.
- iii. Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing EM voltage).
- iv. Unwarranted manipulation of computer software (e.g., forcing calibration or QC data to meet criteria, removing computer operational codes such as the “M” flag, inappropriately subtracting background, or improperly manipulating the chromatographic or spectrophotometric baseline).
- v. Turning off, or otherwise disabling, electronic instrument audit/tracking functions.

QSM 5.2.7: Prohibited Practices

➤ **QSM 5.2.7 d)**

Misrepresenting or misreporting QC samples.

- i. Representing spiked samples as being digested or extracted when this has not been done.
- ii. Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed.
- iii. Failing to prepare or analyze method blanks and the laboratory control sample (LCS) in the same manner that samples were prepared or analyzed.
- iv. Tampering with QC samples and results, including over spiking and adding surrogates after sample extraction.
- v. Performing multiple calibrations or QC runs (including CCVs, LCSs, spikes, duplicates, and blanks) until one meets criteria, rather than taking needed corrective action, and not documenting or retaining data for the other unacceptable data.
- vi. Deleting or failing to record non-compliant QC data to conceal the fact that they were non-compliant.

QSM 5.2.7: Prohibited Practices

➤ **QSM 5.2.7 e)**

Improper calibrations.

- i. Discarding points in the initial calibration to force the calibration to be acceptable.
- ii. Discarding points from an MDL study to force the calculated MDL to be higher or lower than the actual value.
- iii. Using an initial calibration that does not correspond to the actual run sequence to make continuing calibration data look acceptable when in fact it was not.
- iv. Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC criteria or to avoid corrective actions.

QSM 5.2.7: Prohibited Practices

- **QSM 5.2.7 f)**
Concealing a known analytical or sample problem.
- **QSM 5.2.7 g)**
Concealing a known improper or unethical behavior or action.
- **QSM 5.2.7 h)**
Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official.

An Old Case

➤ Intertek Testing Services (ITS), Texas

- Fined 9 million dollars in 2002
- 4 employees/owner given 24-36 months probation
- Unknown thousands of projects affected
- Falsified Superfund data
- Falsified DoD closure site data
- Investigated by:
 - EPA Criminal Investigation Division (CID)
 - EPA National Enforcement Investigation Center (NEIC)
 - EPA Office of Inspector General (IG)
 - US Army CID
 - US Air Force IG

New Case

- A lead poisoning scandal has struck a second US town, with schools closed in *Sebring, Ohio* Monday (Jan 25th, 2016) and the water treatment plant operator **accused of falsifying reports**.
- Initial tests found elevated lead levels in 28 homes and one school in the mid-western village of about 4,400 people, Ohio's environmental protection agency said. It is not clear how long lead has been leaking from the town's pipes.
- The agency said in a statement it has **"reason to suspect that the operator falsified reports"** and has asked the federal Environmental Protection Agency's criminal division for help with the investigation.

EDQW Involvement

➤ Inappropriate Practices – Instances of Reporting:

▪ Laboratory A:

Incorrect background was used for one detector producing incorrect Gross Alpha Results.

▪ Laboratory B:

It was discovered that ten PAH's are not on the laboratory's certified parameter list for SW 846 8270D SIM analysis. These compounds are included on the state's requirement for certification.

▪ Laboratory C:

Improper integrations (calibrations, QC samples, internal standards) had been performed on some reported data limited to volatile analytical methods 524.2, 624 and 8260B/8260C from January, 2012 through March, 2015 and does not apply to all of the data generated during this timeframe. Through data reviews and interviews with laboratory personnel conducted by the Organics Department Manager on March 24-25, 2015, it was determined that a volatiles group leader was directly responsible for the improper practices.

EDQW Involvement

➤ Inappropriate Practices – Instances of Reporting:

▪ Laboratory D:

Manipulation of raw data for GC and GC/MS analyses.

- Not performing the required number of “shakes” and/or not waiting the required period of time between “shakes” of waste water samples.
- Not “spiking” a soil or waste water sample with a known compound in the correct sequence or manner.
- Altering the settings on GC/MS instruments or disregarding calibration protocols.

EDQW Involvement

➤ Inappropriate Practices – Instances of Reporting:

▪ Laboratory E:

On one or more occasion(s), one or more employee(s) in Laboratory's Extractions and Semi-Volatiles laboratories did not strictly follow the approved EPA methods, including:

- Improper peak integrations
- Discarding point in calibration
- "M" flags being removed
- Improper clock settings

Inappropriate Practices Memo

“The EDQW is now requiring all DoD ELAP laboratories to report and submit the associated corrective action on any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM Version 5.0, discovered during any internal or external assessment or investigation to your AB **as soon as practicable**.”

As your AB, we will then have the responsibility of informing the EDQW of the laboratory’s deviation from the requirements of the QSM. Your AB and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties on this matter.”

Resolved?

- What is considered “as soon as practicable” when you are reporting to authorities about potential cases of improper practices?

- Difficult to assess, as each case is different in scope and applicability. For example:
 - South Carolina data breach: Do the Russians have my Social Security Number?

 - Office of Personnel Management (OPM) data breach: Do the Chinese have my Social Security Number?

 - Flint, Michigan water anyone?

QUESTIONS????

For more information:

<https://www.denix.osd.mil/portal/page/portal/EDQW>

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