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Reliable Data = Results Reported Correctly (Accurately and Free of Ambiguity)

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2023 NEMC
August 1, 2023

Introduction

- Importance of Accurate, Objective, and Unambiguous Reporting
  - Stakeholder decisions backed up by reliable data
  - Reduced costs and efficient use of laboratory resources
  - Demonstration of laboratory competency

Introduction

- Reporting Requirements in ISO/IEC and TNI Standards
  - EL-V1M2-2016-Rev2.1 Section 5.10
  - ISO/IEC 17025:2005, Clause 5.10.1
  - Applicable regardless of form of transmittal (hardcopy or electronic)
  - Includes subcontractor reports
  - Exceptions for format (simplified versus formal reports)

- Key Points to Explore
  - Use of data qualifiers
  - Relationship between detection and quantitation limits
  - Re-issuing reports

Objectives

- At the end of the day and going forward,
  - Have clearer and more succinct understanding of reporting requirements
  - Minimize, if not eliminate, ambiguities (misunderstanding and misuse) in analytical reports we create

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Objectives

- At the end of the day and going forward,
  - Trace or retrace what transpired during analysis or during any step of the analytical process, thereby be able to:
    - Explain to clients/stakeholders how data will affect their decision-making
    - Recognize affecting issues that are beyond our control versus those where we can act upon and do act upon those
    - Increase understanding of the why of methods and comply

Objectives

- At the end of the day and going forward,
  - Learn from experiences as well as from mistakes, and do not repeat the mistakes
  - Continuously improve our laboratory operations
  - Meet accreditation requirements and receive your certificate
  - Be a positive contributor to the protection of the environment

Objectives

- Ultimate goal – *Reports must be credible: able to stand on its own, without assumption, such that anybody equally competent can understand what the report conveys*

Key Point – Use of Data Qualifiers

- What are they - Indicator of biases in the data
- Qualifiers help the laboratory tell the story:
  - what happened during analysis
  - difficulties encountered
  - conditions beyond your control
  - corrective actions
  - any limiting factors
  - did you follow the method
  - can you stand by the data you are reporting

Key Point – Use of Data Qualifiers

- As Data User –
  - you read the story
  - attempt to understand the story
  - are data usable for their intended purpose
  - how will the results affect your decision-making
  - do you believe the data
- As Laboratory –
  - what could you have done better
  - lessons learned
  - did you tell your story clearly

Key Point – Use of Data Qualifiers

- As Laboratory – use only qualifiers approved by your organization
  - Be creative, aside from using common qualifiers from the industry, create your own to achieve consistency and enhance efficiency
  - Qualifiers will avoid narratives that could be subject to inconsistencies, misunderstandings, misuse, and grammatical errors

Key Point – Use of Data Qualifiers

- Example Data Qualifiers

Qualifier	Meaning
J	Estimated result that is less than the reporting limit but greater than or equal to the method detection limit
B	Result is also detected in the method blank
D	Sample analyzed at a dilution
E	Result exceeded the calibration range
Y	Result was obtained using a method for which the laboratory does not possess accreditation. Client was previously notified.

Key Point – Use of Data Qualifiers

- Consult clients before using laboratory-specific qualifiers; some clients may require specific qualifiers (especially in EDDs) to be consistent with historical data and have the same meaning among different laboratories
- Some LIMS can "remap" laboratory qualifiers to client-specific qualifiers
  - Reduce errors because laboratory analysts/data reviewers will always see/use the same qualifiers with the same meanings, while clients see the qualifiers they expect and that have meaning to them

Key Point – Understanding Detection and Quantitation Limits

- Quantitation limit (RL, QL, or LOQ) required to be reported
- Detection Limit (MDL, LOD, DL) required when client or method requires and when necessary to interpret the results
  - Example: If reporting data with J qualifier, detection limit is necessary
- Follow approved procedures for determining detection limit and verifications thereof (see analytical method, 40 CFR 136 Appendix B, or TNI Standard)

Key Point – Understanding Detection and Quantitation Limits

- Is there sufficient separation between the two limits (e.g., 2x, 3x)? Did you consider signal to noise ratio (when applicable)?
- Is your lowest calibration point at or below the quantitation level? Is the relative error at the low end of the calibration reasonable?
- Are both limits adjusted when a dilution factor is applied to final results?

Key Point – Understanding Detection and Quantitation Limits

- As applicable, do the quantitation limits meet regulatory levels (e.g., EPA MCLs, DLRs in CA)
- Did you qualify these results? Were they explained in the case narrative?

Key Point - Reissuing Reports

- Why Reissue?
  - Fix clerical errors (obvious typos)
  - Fix errors in report production (add missing samples, add information needed to interpret results)
  - Laboratory becomes aware of an issue that casts doubt on validity of results
- Not every problem discovered after reporting requires reissue; client notification may suffice

Key Point - Reissuing Reports

- When evaluating bias to results due to lab error, remember to consider uncertainty (V1M2 5.4.6)
- Notify clients in writing when internal audit shows results may have been affected (V1M2 4.14.2)
- Establish a policy with time frame for notifying clients of events that cast doubt on the validity of results (V1M2 4.14.5)

Key Point - Reissuing Reports

- Decide whether to issue supplemental or new report
- Supplemental reports must be clearly identified as such
- Add a unique identifier that clearly links the original report to the re-issued report
- Add a statement that the revised report supersedes the original
- Specify what changed and why and by whose authority the change was made

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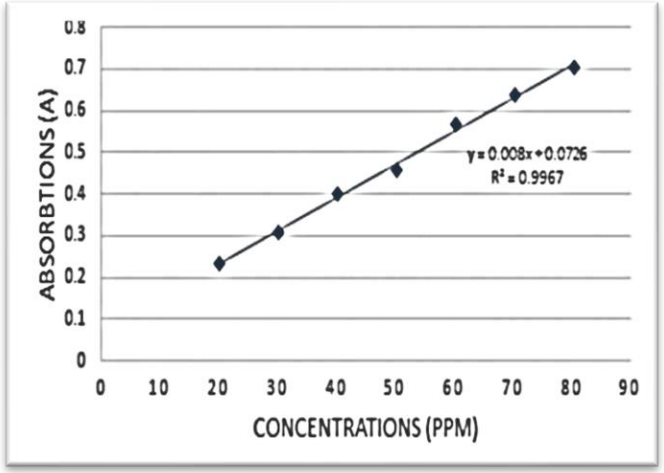
REPORT REISSUE SCENARIOS
What Would You Do?

Scenario #1 - Reissuing Reports

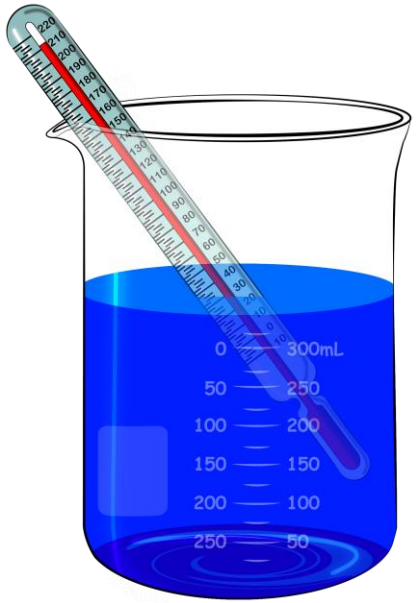
- Laboratory discovers that an error was made when calculating the calibration curve of an ICAL for EPA TO-15. The error biased results low by 10%. The ICAL was dated six months ago and all succeeding CCALs were acceptable.



- Do you need to notify clients of affected samples?
- Do you need to re-issue reports for affected samples?

Scenario #2 - Reissuing Reports

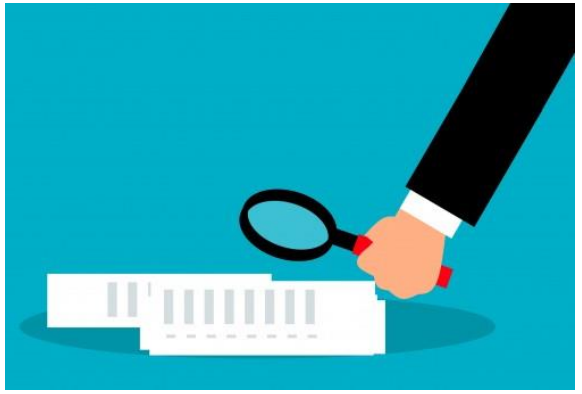
- An internal audit of refrigerator temperature monitoring records shows that on four occasions over the past two months, the temperature recorded for a refrigerator was 3 to 5 degrees above the limit of 6°C.



- Do you need to notify clients of affected samples?
- Do you need to re-issue reports for affected samples?

Scenario #3 - Reissuing Reports

- Laboratory is delayed several weeks reviewing data to conduct its annual verification of the MDL for a regulated compound. When it completes the verification, it finds that the verified MDL is 2.5x the current MDL.



- Do you need to re-issue reports for samples that were reported using the current MDL?
- How do you select reports to re-issue, if any?

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In Conclusion

- The laboratory report is the product of all that went into creating it; the lab's Quality Management System, its qualifications, personnel, equipment, procedures and more
- Proper use of data qualifiers and detection limits lends credibility to the report
- Labs must know how and when to reissue reports
- Communication with clients is essential!

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THANK YOU!