

# National Environmental Monitoring Conference Ensuring Reliable Data

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The Competency of Analysts is a Key Component of Reliable Data

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# **Key Elements of Laboratory Analysis**

- A Quality Management System (QMS)
- Clear Measurement Quality Objectives (MQOs)
- A valid method.
- A competent analyst.
- Effective Quality Control (QC).





# **Key Elements of Analyst Competency**

- Education and Experience
- Technology-specific training as needed
- Training on the TNI standard
  - Data Integrity
  - Quality Control
  - Document Control (SOPs and Records)
- Documented Demonstration of Capability





#### **4.1.5** The laboratory shall

- have technical personnel who have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the procedures for performing tests, and to initiate actions to prevent or minimize such departures;
- have arrangements to ensure that its personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work
- specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests;
- provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test, and with the assessment of the test results.



- **4.13.2.1** The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued, for a defined period. The records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each and checking of results.
- **4.13.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.
- **4.13.2.3** When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.



#### 4.13.3

- All information necessary for the historical reconstruction of data shall be maintained by the laboratory.
- All generated data, except those that are generated by automated data collection systems, shall be recorded legibly in permanent ink.
- **5.2.1** The laboratory management shall ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.



- **5.2.2** The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.
- **5.2.3** The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.



**5.2.5** Management shall authorize specific personnel to perform particular types of sampling, test, to issue test reports, to give opinions and interpretations and to operate particular types of equipment.

#### 5.2.7 Data Integrity Training

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. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution.



#### **Modules 3-7 – Initial and On-Going Demonstration of Capability (DOC)**

- □ Requirements vary slightly by Module but all require satisfactory initial DOC before analyzing any samples and then annual re-verification.
- Generally include some combination of:
  - Replicate Laboratory Control Samples (at least 4)
  - On-going QC
  - Proficiency Test samples





## **Documentation Requirements**

- **5.2.4** The laboratory shall maintain current job descriptions for technical and key support personnel involved in tests.
- **5.2.5** The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

#### 5.2.7 Data Integrity Training

The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

Modules 3-7 Initial and on-going Demonstration of Capability



# **Examples of Poor Analyst Competency and the Impact**

- ☐ The examples follow
- Citation to TNI standard provided.





#### **Pesticide Misidentification**

- Analyst incorrectly identified dieldrin in soil samples because the analyst did not know how to establish retention time windows correctly.
- Engineering firm performed unnecessary remediation.

#### **QMS Failures**

4.1.5 – Management

4.2.8.4 – Experienced personnel

5.2.1 – Management of personnel

1.6 (Module 4) – Demonstration of Capability





# 6 and 7-Day BOD

- Analyst did not want to come in on weekends and take readings for samples set up on Tuesday and Wednesday.
- Oxygen levels measured on Monday resulting in 6 or 7-Day BOD.

#### **QMS** Failure

5.4.1 – Deviation of Test Methods





# Why Did Annie Dookhan Lie?

- □ 21,587 cases overturned in MA Crime Lab.
- Dookhan did not test samples but wrote down what the police suspected as the result.
- Productivity 5 x greater than other laboratory staff.
- If police did not write something down, Dookhan would spike sample with cocaine and test.
- Sentenced to prison for 3 years.

#### **QMS Failures**

4.1.5 – Laboratory

#### Management

4.2.8 – Data Integrity

4.13.2 – Technical Records

5.2.1 – Personnel

5.10 - Reporting Results





# Recommended Best Practices for Ensuring Analyst Competency

- ☐ Training Schedules
- Dedicated trainer
- ☐ Training Files included in the internal audit
- Beyond the CDOC





# **Closing Thought**

Using analysts with demonstrated competence greatly improves the reliability of the reported result by increasing confidence that the laboratory knows what it is doing.

Data you can

trust.





### **THANK YOU!**

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