

# Ensuring the Generation of Known and Documented Field Data

Data Traceability

August 10, 2017

---

# Abstract

- The presentation provides information to ensure data quality for field sampling and measurements. Adopting the TNI field activity standard is one way to ensure the generation of known and documented quality data.
- The data generated for any regulatory or self monitoring is only as good as the sampling design and collection process. The laboratory cannot improve the data quality if the sampling design and collection is not performed by a competent organization.
- Ensuring the sample is representative of the material and fit for purpose are integral parts of the design and collection process. The TNI standard development process ensures all stakeholders can collaborate and provide input to the standard.

# Oversight is coming!

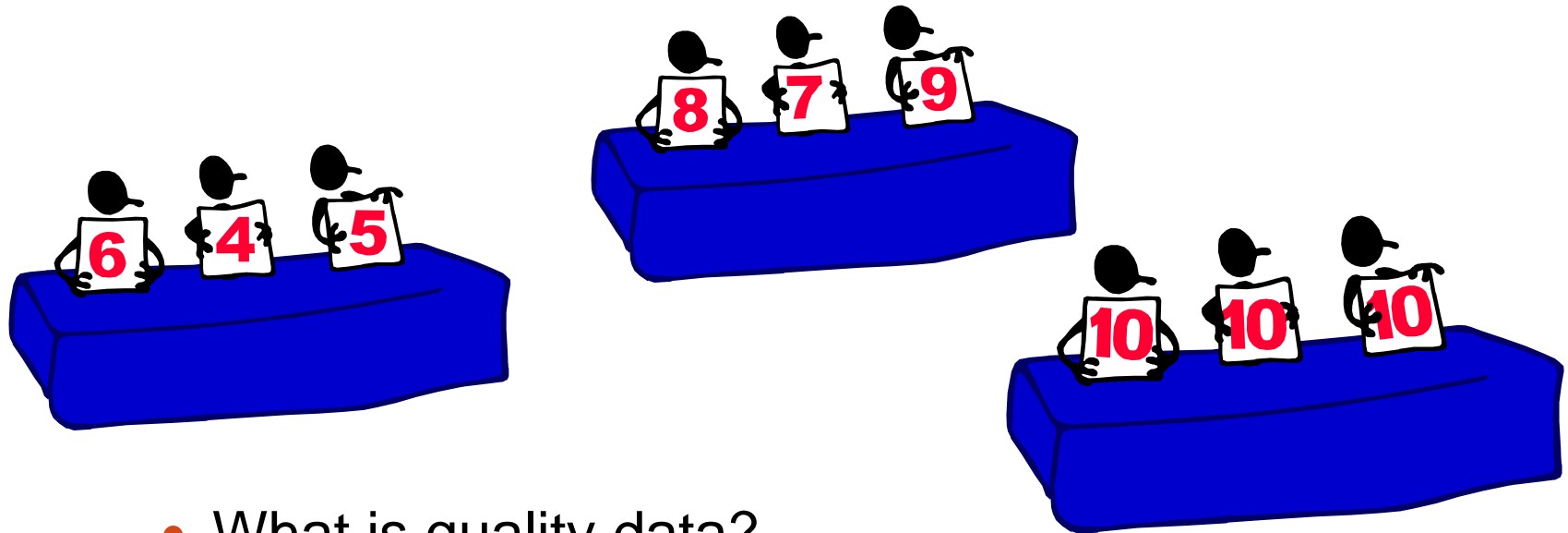
- Now is the time to be involved to set your destiny
- Field sampling and testing organizations (FSMO) must prepare so they are ready
- Many papers have identified that over 90% of the data variability is from field operations
  - a significant amount can be reduced with proper planning, management controls, quality assurance and oversight.
- More regulatory agencies are now looking at the sampling operation as one of the contributors to the generation of quality data
- If you are an FSMO
- **Do you generate data of known and documented quality?**

# What are field activities?

- Your organization needs to define.
  - Sample collection planning
  - Sample collection
  - Sample transport to laboratory
  - Measurements made in:
    - Field – no structure
    - Mobile structure
    - Not a fixed lab....

<http://www.epa.gov/fem/pdfs/fem-lab-competency-policy.pdf>

# How good is the data?

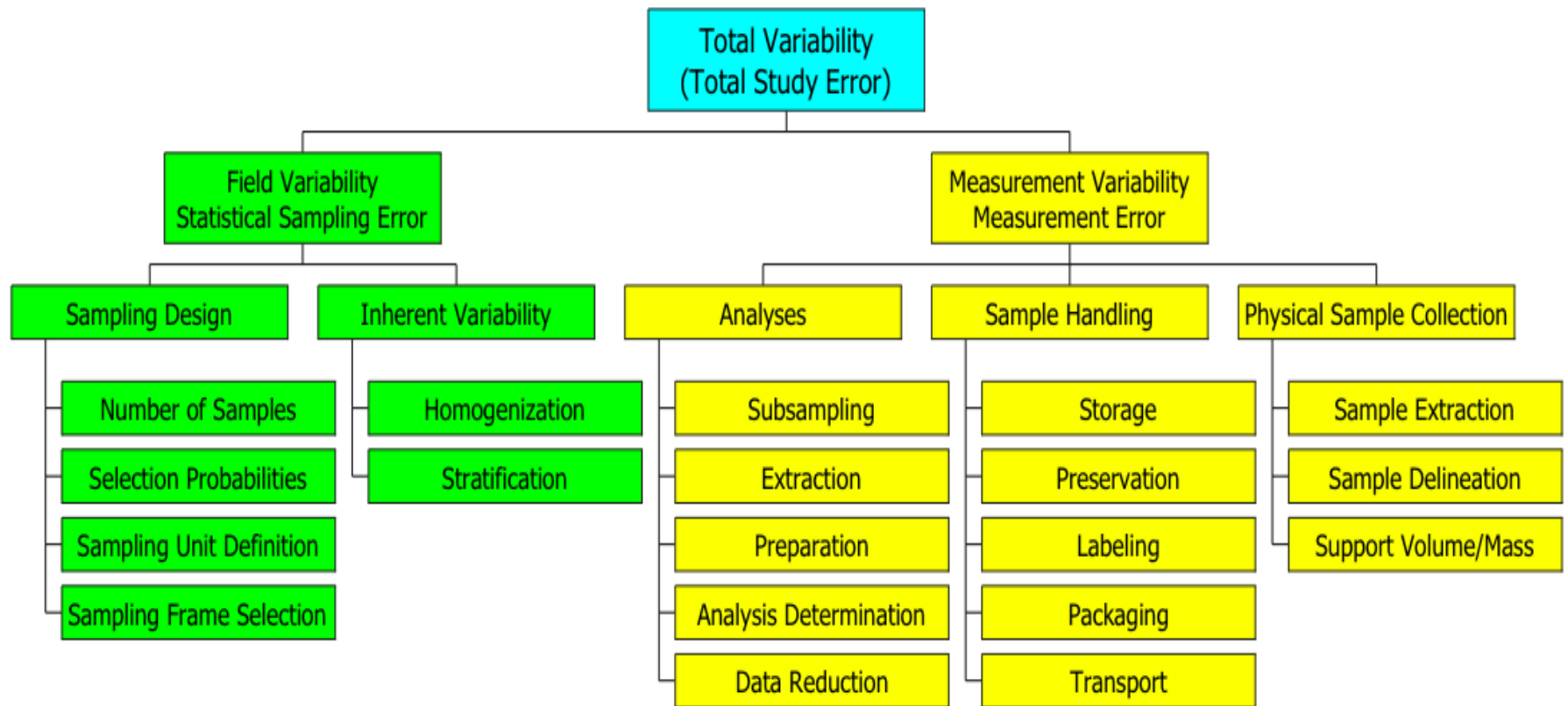


- What is quality data?
- How do you defend the data?

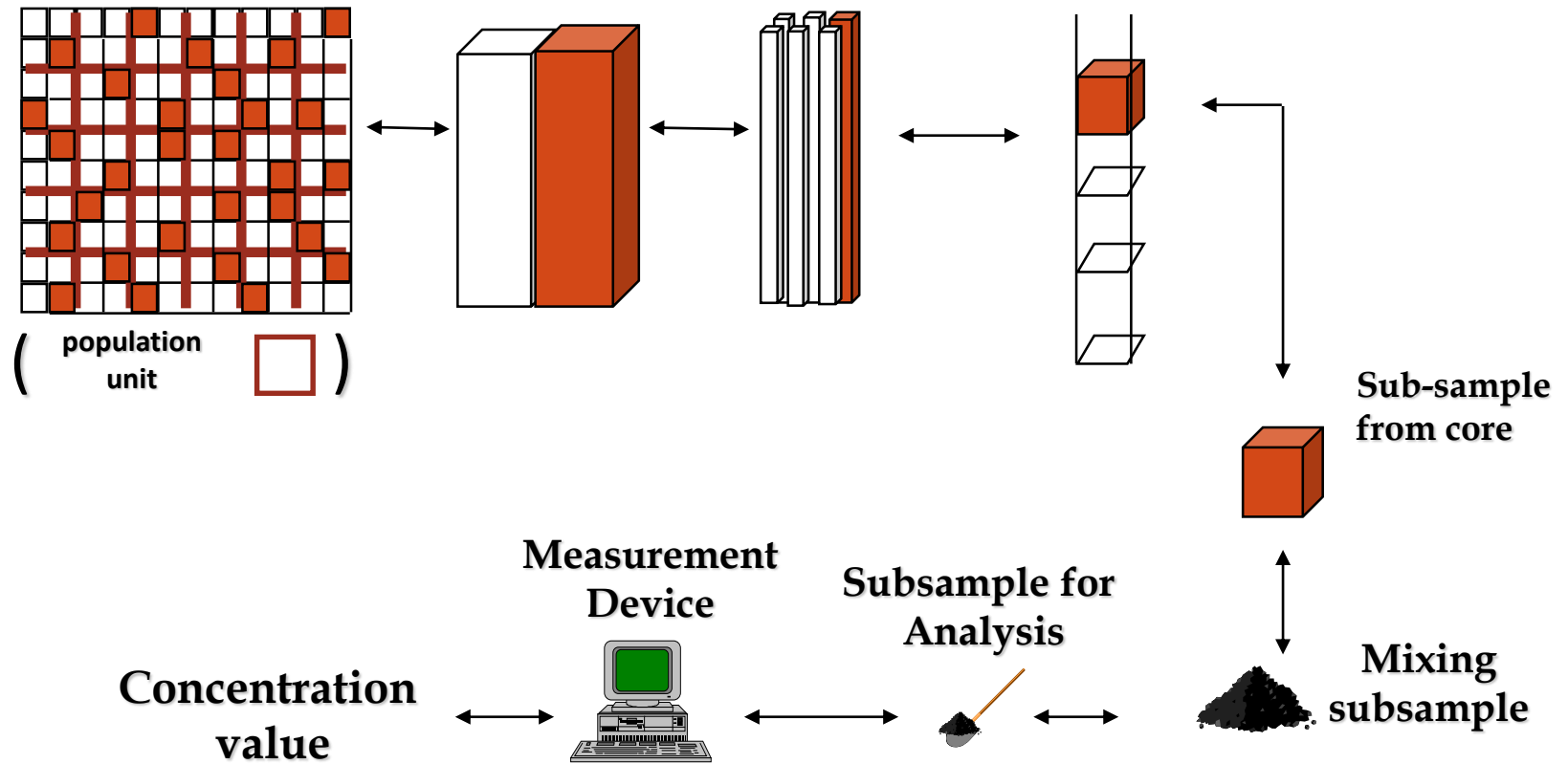
# Demonstrate Your Competency via Data Traceability

- Client audit/review process (second party)
- Oversight by project officer (government oversight)
- Accreditation – following consensus process for recognition and oversight
  - Third party
  - State or regulatory program
  - Accreditation body process with input from all stakeholders
- The TNI standard provides a mechanism to develop requirements

# Measurement per EPA



# Variability in Data



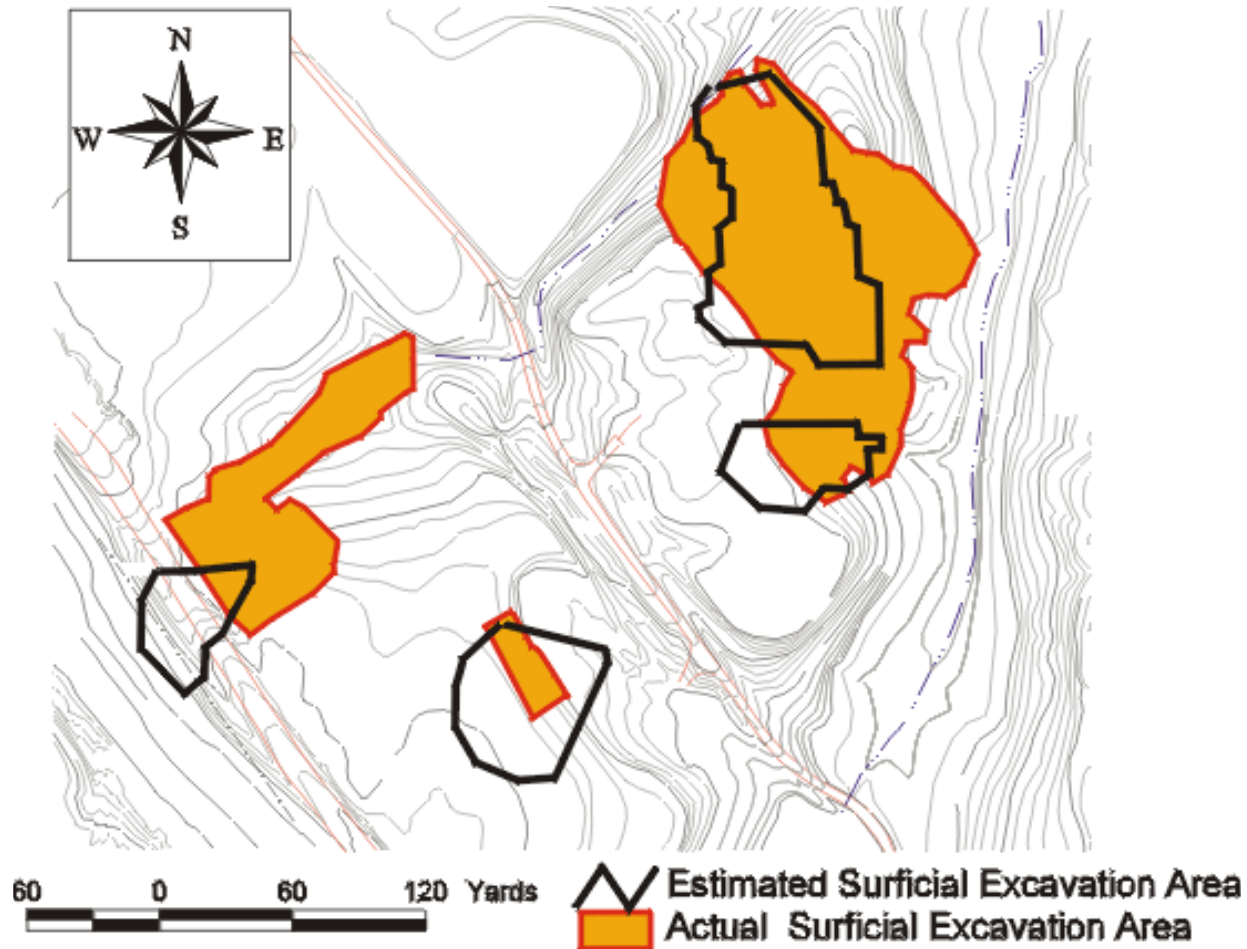


# Some Basic Statistical Concepts

- Statistical Modeling
- Summary Statistics
- Sample Statistics
- Skewed Field Data
- Graphical Techniques
- Two-variable Statistics
- Hypothesis Testing
- Statistical Sampling Designs

**How do you determine the  
number of samples to  
collect?**

Where and how do you sample if the contamination distribution looks like this?



# Records and Data

- Records
  - Codes or regulatory program provides specific details to be maintained
  - FSMO defines how this is done
- Data and Information
  - The final result must be traced to the:
    - Materials used to calibrate and determine the result
    - Equipment used to generate the result
    - Method used to produce the result
    - Sample analyzed and location taken
    - Sample collection method and procedure
    - Field Observations

# Scientific Data Defensibility

- Where is your plan for determining the samples collected are representative?
- When the data are collected will it be necessary for making the decision or solving the problem>
  - *Is the evidence based on testable theory or technique?*
  - *Has the theory or technique been peer reviewed?*
  - *Does the technique have a known error rate and standards controlling its operation?*
  - *Is the underlying science generally accepted?*

*Reference Manual on Scientific Evidence, Third Edition, The National Academies Press, Washington, DC*  
([www.nap.edu](http://www.nap.edu)) ISBN-13: 978-0-309-21421-6

# Regulatory Methods

- 40 CFR 136
- 40 CFR 141
- Other
- Selecting the method source defines the
  - Quality Control
  - Calibration
  - Sampling
  - Data use – Screening or definitive
  - Other requirements
  - Do you have a choice?

# Simple Procedure for Field Use

**Table 5.1-2. Sampling procedure—temperature, pH, conductivity and dissolved oxygen.**

1. Check meter and probes and calibrate according to manufacturer's specifications.
2. Check the calibration against the provided QCS solution for pH and conductivity and record the results on the field sheet as the QCS Measured value. This should be done at least once a week.
3. Record the true value of the QCS solution from the stock solution container on the field sheet as QCS True.
4. Samples are taken mid-channel, at the X site, at a depth of 0.5 meters or at a mid-depth if less than 1 meter deep.
5. Lower the sonde in the water and measure DO, pH, temperature, and conductivity at 0.5 m depth.
6. Record the measurements on the Field Measurement Form.
7. Flag any measurements that the team feels needs further comment or when a measurement cannot be made.
8. If sampling at the X-site is not possible, move to another part of the reach to take the measurements (as close to the X-site as possible), record the letter of the nearest transect in the "TRANSECT" box and more detailed reasons and/or information in the Comments section.

# Records – Reason

- Historical reconstruction
- Personnel identified
- Equipment, test method, sample handling, sampling
- Verification of data
- Retrieval of information
- Recorded promptly – legibly
- Changes to records, including electronic files
  - Why were corrections made?

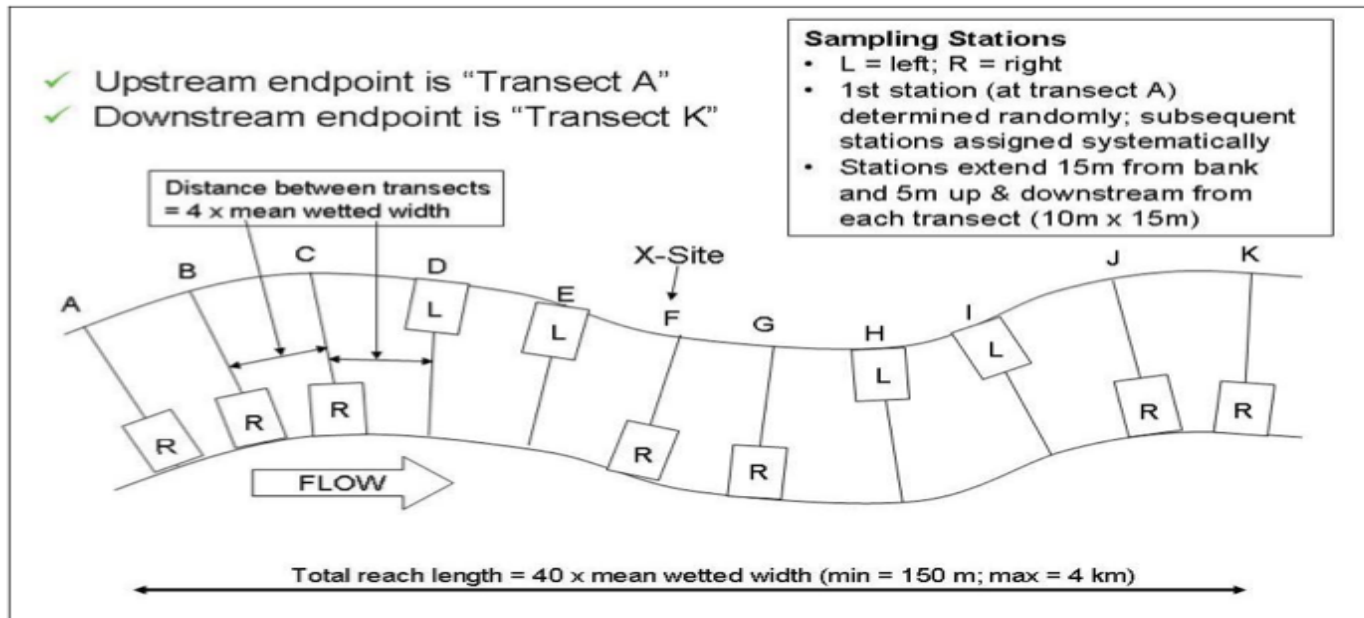


Figure 4-5. Sampling reach features for a non-wadeable site.

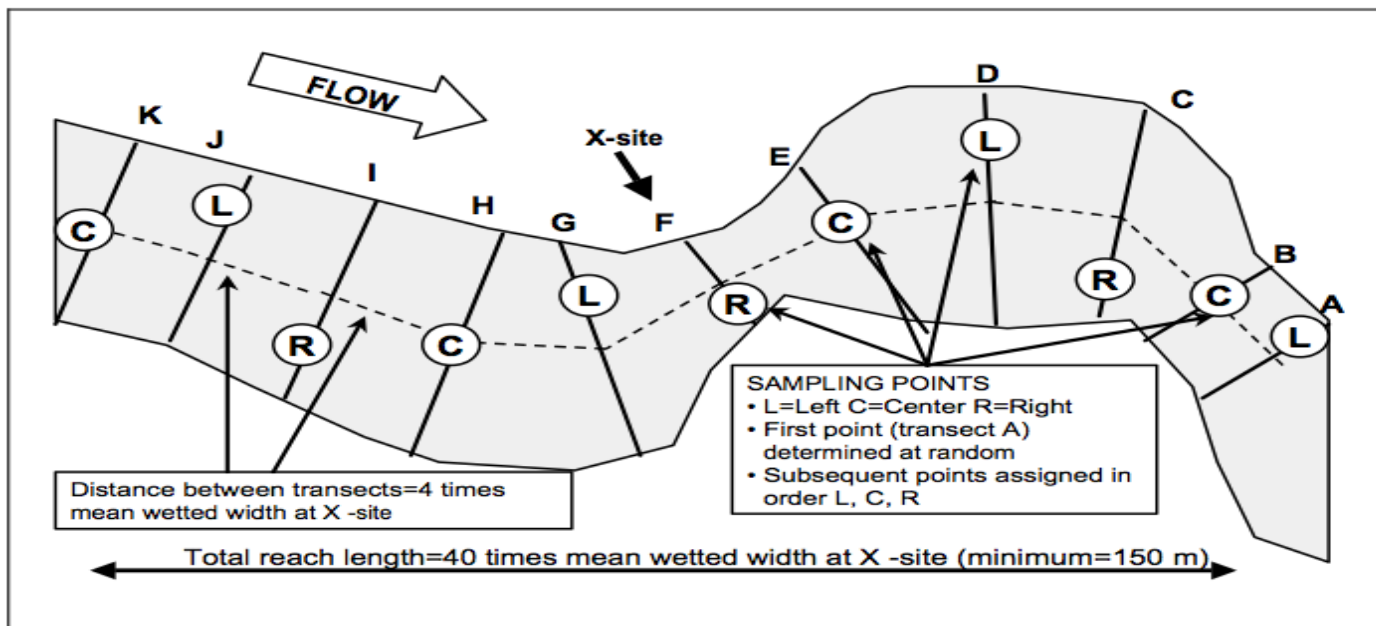


Figure 4-6. Sampling reach features for a wadeable site.



# Reporting Field Activities

- Field reports must be complete and reflect the activities completed
- The details presented is dependent on customer requests
- All items defined in TNI V1 5.10 must be available even if not reported.

# Field Measurement Qualifiers

## Data Qualifiers (Flags)

Use only defined flag codes and record on data form in appropriate field.

K = Measurement not attempted or not recorded.

Q = Failed quality control check; remeasurement not possible.

U = Suspect measurement; remeasurement not possible.

$F_n$  = Miscellaneous flags ( $n = 1, 2$ , etc.) assigned by a field team during a particular sampling visit (also used for qualifying samples).

Explain reason for using each flag in comments section on data form.

# Benefits to the FSMO

## Establishes Foundation of Management Systems

- Clearly define roles and responsibilities
- Establish clear procedures for documentation and maintaining control of documents and records
- Clear procedures for contracts, subcontracting, purchasing and the evaluation of all aspects of the operations
- Helps to ensure data defensibility

# What does it take for a FSMO to become accredited...

- Purchase Standard – Available on website
- Prepare – do not wait to begin working towards the Standard
- Talk to recognized Accreditation Bodies
  - Find the best fit for your organization
  - *VISIT TNI website:* [www.nelac-institute.org](http://www.nelac-institute.org)
- Apply for accreditation
- Follow the process
- Achieve accreditation

# Continuous Process Improvement

**Requirements set a clear path to improvement**

**Tools are laid out**

- Corrective action
- Preventive action
- Complaint tracking
- Review and control of non-conforming work

**Helps facilitate improved quality!!!**

# Remember

Following the requirements  
of the TNI FSMO Standard  
produces data of known and  
documented quality  
from the field

# Questions / Answers

- Any questions ?
- [mmoore@advancedsys.com](mailto:mmoore@advancedsys.com)

