Disclaimer: The information in this guidance document does not supplant to provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252 or the TNI Standard. This document is a tool to help laboratories comply with Chapter 252 and the TNI Standard. If there is any disagreement between the contents of this document and Chapter 252 and the TNI Standard, the regulations or standard shall prevail. This document outlines the Department of Environmental Protection's ("Department") Laboratory Accreditation Program ("LAP") of the Department's expectations regarding the reporting and notification requirements for microbiological testing of SDWA compliance samples. Specifically, the analysis dates and times, validation and invalidation of results and public notification.

I. What is traceability?

A. Traceability is defined as "*the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project"* (2016 TNI VIM2 3.1).

Think of traceability as the ability to perform "historical reconstruction" of the data. Consider a "front-to-back" and "back-to-front" approach when evaluating data traceability.

- Can you "TRACE", track, or reconstruct the historical details of a sample from the moment it arrived at the lab until a result was generated?
- Can you determine exactly who handled the sample, when it was analyzed, what reagents were used, how they were prepared, who made them, and whether the reagent's components were unexpired chemicals of the appropriate concentration and volume or weight?
- Can you determine the identity of the instrument used for analysis, if the laboratory has more than one instrument in service capable of that analysis at a given time?
- Can you determine the calibration status of the equipment used to obtain the result?
- Can you determine that data were managed according to documented protocols and verified appropriately?
- Can you do all of the above by using only the documentation available in the laboratory?

These questions help explain "front-to-back" traceability. Likewise, a final analytical result should be traceable by "backing up" through the process from the final reported result all the way to the receipt of the sample in the laboratory, by only reviewing the documentation produced by the laboratory….all without speaking to the staff involved. Thinking in terms of "front-to-back" and "back-to-front" traceability allows one to consider all of the "pieces and parts" that become part of building good traceability documentation in the laboratory.

II. How do NIST reference materials apply to traceability?

A. "NIST-traceable" reference material is a commercially produced reference material with a well-defined traceability linkage to existing National Institute of Standards and Technology (NIST) standards. This traceability linkage is established and maintained via criteria and protocols established by NIST to meet the needs of the community to be served. The use of NIST-traceable reference materials is not equivalent to establishing procedures for ensuring traceability of measurements. NIST reference materials are only one component of the documentation used in defining traceability of laboratory results.

III. Why does my laboratory need to establish procedures for ensuring traceability of measurements?

A. Traceability ensures the legal defensibility of the laboratory's data and helps the laboratory troubleshoot nonconformance issues.

Examples:
1) An analyst may investigate an issue for an analytical batch in which all of the quality control samples failed to meet the method acceptance criteria. The analyst reviews the reagent preparation log and discovers that the wrong type of acid was used for preparing the sample digestion solution.
2) Investigation of a failed proficiency testing (PT) result may reveal, through sample preparation records, that the PT sample was prepared using an incorrect dilution.
3) Trending of QC data reveals distinct patterns in QC data. The patterns can be linked to an individual analyst because QC records included the analyst's initials. Laboratory management can address the QC issue by working directly with one analyst to troubleshoot the nonconforming data.

IV. How can I demonstrate that my laboratory has established procedures for ensuring traceability of measurements?

A. Develop a process or a procedure to document the calibration and the use of **reference equipment** and **support equipment**, such as reference thermometers, working thermometers, weights, balances, autoclaves, mechanical pipettes, and bottle-top dispensers.

i. Weight records: Reference standards must be calibrated by a body that can provide traceability (2016 TNI V1M2 5.6.3.1). Where commercially available, this traceability shall be to a national standard of measurement (such as NIST).

a. Laboratories which have balances have weights used for balance verification ("working measurement standards", or "working weights"), and may also have weights used for verification of the working weights (considered reference standards or "reference weights"). The frequency at which reference weights and working weights are calibrated must be established and included or referenced in the laboratory's quality manual.

b. The laboratory must be able to provide a documented link between support equipment check documentation and the specific weights in use. This can be accomplished by recording the serial number of the weight set on the support instrument check log (where balance checks are recorded). *Note that this link may be accomplished using other approaches as well.*

ii. Thermometer records: Reference standards must be calibrated by a body that can provide traceability (2016 TNI V1M2 5.6.3.1). Where commercially available, this traceability shall be to a national standard of measurement (such as NIST).

c. Thermometers used for daily temperature readings are considered support equipment and require annual calibration (2016 TNI V1M2 5.5.13.1.d).

d. The laboratory must be able to provide a documented link between support equipment check documentation and the specific thermometers in use. This can be accomplished by recording the serial number of the thermometer on the support instrument check log (where daily refrigerator, incubator, oven checks, etc. are recorded). *Note that this link may be accomplished using other approaches as well.*

e. Some laboratories have NIST-traceable thermometers, for performing annual verification of working thermometers, and these are considered “reference standards”. The frequency at which NIST-traceable reference thermometers are calibrated should be included or referenced in the laboratory’s Quality Manual (2016 TNI V1M2 4.2.8.4.a). Note that reference thermometers are to be used for calibration of working thermometers only, and for no other purpose (2016 TNI V1M2 5.6.3.1).

iii. Mechanical volumetric dispensing devices such as non-class A burettes, mechanical pipets, and bottle-top dispensers shall be checked for accuracy on at least a quarterly use basis. (2016 TNI V1M2 5.5.13.1.e). Glass microliter syringes are to be considered in the same manner as Class A glassware.

a. When quantitative results are dependent on the equipment accuracy, the laboratory may benefit by demonstrating traceability to each mechanical volumetric dispensing device used. One approach to managing this aspect of traceability is by recording on the bench sheet the serial number or other assigned identification number of the dispensing device. An example of a dispensing device on which quantitative results are dependent is a micropipettor used to measure sample volume. Traceability to the micropipettor will benefit the laboratory in a situation where corrective action is being conducted in response to quality control failures, and the cause of the issue is determined to be a faulty micropipettor.

B. Develop procedures to document all information relating to **analytical instruments used to process a sample result,** such as pH meters, dissolved oxygen meters, discrete analyzers, spectrophotometers, or ICPs (2016 TNI V1M2 4.13.3.f.vi). Analytical records must uniquely identify the instrument used for each analysis (2016 TNI V1M2 5.5.5.b). This includes unique identification of replaceable determinative parts such as an electrode or probe.

C. Develop procedures to document the receipt and use of **purchased standards, reagents, and consumables** such as filters and sample bottles. The following procedures are common approaches used to successfully establish this aspect of traceability:

i. Keep certificates of analysis (if available) (2016 TNI V1M2 5.6.4.2.a). The laboratory may request the certificate of analysis when ordering or go to the company’s website and download the current certificate of analysis.

ii. Retain records for all standards, reagents, reference materials, and media including the following information (2016 TNI V1M2 5.6.4.2):

a. Manufacturer/ vendor
b. Certificate of analysis (if available)
c. Date of receipt
d. Recommended storage conditions
e. Expiration date *(unless its reliability is verified by the laboratory)*
f. For media only, records must also contain lot number, type and amount of media received, and the pH of the media (2016 TNI V1M5 1.7.3.1.b).

iii. Assign a unique identifier to each reagent and standard received. This unique identifier is recorded in the receipt records as well as on the container. The following are examples of unique identifiers that may be used:

a. An abbreviation representing the laboratory department, such as “MET” for metals, followed by the reagent name and receipt date: “MET-HCl-032112”: identifies hydrochloric acid received March 21, 2012 in the Metals section of a laboratory.

b. The reagent name followed by the manufacturer's lot number: "HCl-691532": hydrochloric acid with lot number 691532.

c. An abbreviation such as "STD" for stock standard, followed by the analyte and lot number: STD-TKN-256148: TKN standard lot number 256148. If more than one container of the same lot is received, a letter can be added to the end of the unique identifier to distinguish each container, such as "STD-TKN-256148a" and "STD-TKN-256148b". *Note that unique identifiers may be assigned using other approaches as well.*

iv. Establish documentation that facilitates historical reconstruction and identification of the PURCHASED standards and reagents used for each analysis (2016 TNI V1M2 4.13.3.f.xi). The unique identifier can be recorded on the laboratory's bench sheets or sample preparation logs, providing a link to the preparation information so that a data reviewer can trace back to the origin of stock chemicals. An alternative to listing individual unique identifiers on bench sheets is to note in the reagent log "Date In Use" and "Date Out of Use." *Note that this may be accomplished using other approaches as well.*

v. Maintain records that supply, reagent, and consumable purchases are checked upon receipt to ensure that they comply with standard or method specifications (2016 TNI V1M2 4.6.2). In other words, verify that you received what you actually ordered and that you ordered the correct product. This verification may be documented on the packing slip, which is kept on file, or in some other manner.

D. Develop procedures to document the preparation and use of all **reagents, standards, and media prepared by the laboratory**. The following procedures are common approaches used to successfully establish this aspect of traceability:

i. Assign a unique identifier and expiration date to each of the PREPARED reagents and standards. The laboratory should ensure that **all standards** are included in this process. Examples of standards include:

a. Calibration standards (including Continuing Calibration Verification (CCV) and second source standards (Initial Calibration Verification (ICV))

b. Spiking standards (Matrix Spike (MS), Surrogate, Internal)

c. Quality control standards (QCS) / laboratory control standards (LCS)

d. Stock standards

e. Intermediate or working standards

f. Instrument performance check (IPC) solutions.

ii. The unique identifier and expiration date are recorded in the preparation records as well as on reagent and standard containers (2009 TNI V1M2 5.6.4.2.d).
Examples of unique identifiers include:

a. For a matrix spike, the sample ID followed by an abbreviation such as "SPK": "FE-030112-SPK*".*

b. For each standard in a calibration curve, an abbreviation such as "CAL1", "CAL2", or "CAL3" followed by the preparation date: "CAL1-030112".
Note that unique identifiers may be assigned using other approaches as well.

iii. Document reagent, standard, and media preparation details are recorded in a log or on the bench sheet to include the following information (2016 TNI V1M2 5.6.4.2.c):

a. Source reagent unique identifier

b. Source reagent volume(s) used

c. New reagent unique identifier

d. New reagent final volume

e. Preparation date

f. Expiration date
g. Chemical name (identity)
h. Preparer
i. Solvent identification (such as deionized water)
j. For microbiological media only, records must also contain type and amount of media prepared, lot number, and final pH of the media (2016 TNI V1M5 1.7.3.1.b).

iv. Establish documentation that facilitates historical reconstruction and identification of the LABORATORY-PREPARED standards and reagents used for each analysis (2016TNI V1M2 4.13.3.f.xi). The unique identifier can be recorded on the laboratory's bench sheets or sample preparation logs, providing a link to the preparation information so that a data reviewer can trace back to the origin of stock chemicals. An alternative to listing individual unique identifiers on bench sheets is to note in the reagent log "Date In Use" and "Date Out of Use." *Note that this may be accomplished using other approaches as well.*

E. Maintain documentation of personnel responsible for sample collection, sample receipt, sample preparation, sample analysis, and data verification (2016 TNI V1M2 4.13.2.1). The reason for the signature or initials shall be clearly indicated in the records such as "sampled by," "prepared by," or "reviewed by" (2016 TNI V1M2 4.13.3.g.ii).

F. Maintain records of all sample preparation including but not limited to cleanup, digestion, incubation (times in and out), sample volumes or weights used, instrument printouts, meter readings, and calculations (2016 TNI V1M2 4.13.3.f.ix).

G. Summarize the laboratory's traceability procedures within the Quality Assurance Manual (2016 TNI V1M2 4.2.8.4.h). If traceability procedures are described in individual standard operating procedures, this quality manual requirement can be met with a brief summary referencing the associated documents.