Status of Proposed ANSI/ANS Standard for Radioanalytical Data Verification and Validation

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This paper will describe the background and the current status of the proposed ANSI/ANS 41.5 Standard for Radioanalytical Data Verification and Validation. This standard will be a consensus standard that specifies criteria and processes for determining the validity of radioanalytical results as input to process control site characterization, waste acceptance criteria, waste certification, litigation and other applications as deemed necessary. This standard will provide a minimum set of checks and tests that will ensure a consistent approach for validation of data produced by any radioanalytical laboratory for waste management, environmental remediation and process control. This standard should eliminate many of the inconsistencies in the approaches, evaluation algorithms, parameters evaluated, and qualifiers in existing site specific data verification and validation programs.

This standard establishes criteria for validating radioanalytical data for waste management and environmental remediation activities. This standard applies to data generation process for field measurements and radioanalytical laboratories, which require independent review as specified by the data quality objectives (DQOs). Some of the elements of this standard apply to non-destructive assay and in-situ measurements. This standard does not apply to non radioassay measurement methods (i.e., ICP-MS, KPA, X-Ray diffraction, etc).

The standard is being developed based on the concept of a data life cycle. The data life cycle begins when the Data Quality Objective (DQO) process is used to develop sampling and analysis plan (SAP), laboratory statement of work (SOW), and/or the quality assurance program plan (QAPP) sufficient for the decision rule. These documents are used to set the criteria for field sampling and laboratory analysis. The life cycle continues through Compliance Verification, Validation and Data Quality Assessment.

Compliance verification is the process of checking data to assess that they are complete, consistent, correct, and compliant with a standard of contract. Compliance assessment provides an explanation of the data's contract compliance for payment and reports on the areas of noncontract compliance. Compliance verification does NOT qualify the data. Compliance assessment is comprised of verification of data packages, laboratory audits, and desk (data) audits. The Compliance Verification step includes input from the laboratory data package, field data, laboratory or desk audits, performance evaluation samples.

Validation is the process of providing a level of confidence in the reported analyte concentrations and

its associated uncertainty. Validation is analyte and sample specific and extends beyond method or contractual compliance. Validation produces a data set with a limited number of qualifiers associated with the result. Qualifications are made based on the data's fitness for intended use as defined by the DQOs.

The working group is working hard to complete the first draft of the standard. It is anticipated that the first draft will be ready for submittal through the ANSI consensus process for ballot in 1999. After resolution of comments by all ANSI review committees, the standard will be available for public review and comment. When the period of comment is complete, an updated version will be published.