

American Nuclear Society

**verification and validation of radiological
data for use in waste management
and environmental remediation**

an American National Standard



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American Nuclear Society
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**American National Standard
Verification and Validation of Radiological Data for
Use in Waste Management and Environmental Remediation**

Secretariat
American Nuclear Society

Prepared by the
**American Nuclear Society
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Working Group ANS-41.5**

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Foreword

(This Foreword is not part of American National Standard “Verification and Validation of Radiological Data for Use in Waste Management and Environmental Remediation,” ANSI/ANS-41.5-2012.)

The American Nuclear Society (ANS) Nuclear Facilities Standards Committee (NFSC) is responsible for development of American National Standards Institute (ANSI) standards for nuclear facilities, including criteria and operations required for environmental remediation of nuclear facility sites that have become contaminated. The ANS Subcommittee on Decommissioning and Site Remediation Standards manages the development and maintenance of standards that address the cleanup of radioactive materials and radioactivity mixed with hazardous substances. This subcommittee has authorized a working group to develop a new ANSI/ANS standard, ANSI/ANS-41.5-2012, for verification and validation of data from radiological analysis supportive of waste management and environmental remediation. The verification process will be called compliance verification in this standard. Compliance verification may involve compliance to written analytical specifications (e.g., statement of work, contract, project plans) but may also involve compliance to programmatic or project-specific requirements. Therefore, this standard does not assume or require that the laboratory work be performed under contract.

This standard provides requirements and recommended practices for determining the validity of radioanalytical data for waste management and environmental remediation. These applications will include site characterization, waste acceptance, waste certification, waste treatment design, process control, 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 compliance verification and validation of data produced by any radioanalytical laboratory. This standard should eliminate many of the inconsistencies in the approaches, evaluation algorithms, parameters evaluated, and qualifiers used in existing site-specific data compliance verification and validation programs.

The requirements of this standard apply only to independent compliance verification and validation processes and should not be construed to apply to any actions taken by laboratories to internally generate or review data, including audits and performance evaluation studies. Other standards are available that provide quality and performance requirements for radioanalytical laboratories [e.g., ANSI N42.23-1996 (R2003), “Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories”]. However, this standard expects that certain laboratory quality control (QC) and programmatic quality assurance (QA) measures have taken place that feed data for review by the data verifiers and validators. The interface of these QA/QC measures with the compliance verification and validation process will be discussed in Sec. 3 of this standard. Since this standard does not place requirements on laboratories or on waste management and environmental remediation programs, the points of interface in Sec. 3 are necessarily listed as only recommendations, and all requirements are contained in Secs. 4 through 7 of this standard.

While this standard will provide a minimum set of checks and tests for compliance verification and validation of data, the acceptance criteria for the test and checks are intentionally not provided in most cases. This is because each waste management or environmental remediation program or project may have unique measurement quality objectives (MQOs) based on the intended use of the data. This standard has been developed with the assumption that a proper data quality objective (DQO) process has been used by the project to define the quality of data needed for the decision process and to develop corresponding MQOs of

accuracy, precision, sensitivity, selectivity, and representativeness to be met. Therefore, set limits for QC parameters and many other acceptance criteria will not be recommended in the standard, but rather the user will be referred to the limits established by the DQO process. This approach will allow data qualification to be based on how factors such as error, bias, lack of precision, lack of sensitivity, or lack of selectivity affect the decision process. The DQO process should also provide guidance for the frequency, percentage, and extent of data validation. This standard will incorporate an evaluation of data end use and action levels throughout the qualification process. This approach will prevent unnecessary rejection of data for minor quality problems.

This standard contains four appendices, which are informative and contain additional description of the relationship of the programmatic and laboratory QA/QC measures with the compliance verification and validation processes. This foreword is not part of the standard.

This standard might reference documents and other standards that have been superseded or withdrawn at the time the standard is applied. A statement has been included in Sec. 8, "References," that provides guidance on the use of references.

This standard does not incorporate the concepts of generating risk-informed insights, performance-based requirements, or a graded approach to QA. The user is advised that one or more of these techniques could enhance the application of this standard.

The working group would like to gratefully acknowledge the contributions by Jason C. Jang, who died prior to the completion of this standard.

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Verification and Validation of Radiological Data for Use in Waste Management and Environmental Remediation

1 Purpose and scope

1.1 Purpose

This standard¹⁾ specifies verification and validation criteria and processes for determining the validity of radioanalytical data for waste management and environmental remediation. These applications include site characterization, waste acceptance, waste certification, waste treatment design, process control, litigation, and other applications requiring data verification and validation. This standard provides a minimum set of checks and tests to be performed by a reviewer independent from the laboratory data generator. These checks and tests will ensure a consistent approach for independent verification and validation of data produced by any radioanalytical laboratory. This standard should eliminate many of the inconsistencies in the approaches, evaluation algorithms, parameters evaluated, and qualifiers used in existing site-specific data verification and validation programs.

1.2 Scope

This standard establishes criteria and processes for verification and validation of radioanalytical data for waste management and environmental remediation activities. It applies to the independent review of the data generation process for field measurements and radioanalytical laboratories. This standard sets the requirements for how the data are reviewed and qualified against the data quality requirements [e.g., measurement quality objectives (MQOs)] that are established by the project to meet their intended use. While this standard does not specifically address all nondestructive assays and in situ measurements, the general principles and some of the elements of

this standard may apply. This standard does not address nonradioassay measurement methods (e.g., inductively coupled plasma–mass spectroscopy, kinetic phosphorescence analysis, X-ray diffraction).

2 Acronyms and definitions

2.1 List of acronyms

ANSI: American National Standards Institute

APS: analytical protocol specification

CLP: contract laboratory program

COC: chain of custody

CSU: combined standard uncertainty

DER: duplicate error ratio

DL: decision level

DOE: U.S. Department of Energy

dpm: disintegrations per minute

DQA: data quality assessment

DQO: data quality objective

L_c : critical level

LCS: laboratory control sample

LCS %D: laboratory control sample percent difference

LLD: lower limit of detection

MARLAP: Multi-Agency Radiological Laboratory Analytical Protocols Manual

MDC: minimum detectable concentration

¹⁾The current standard, ANSI/ANS-41.5-2012, is hereinafter referred to as “this standard.”