METHODOLOGY FOR QUALIFICATION OF RADIOLOGICAL AND HAZARDOUS WASTE DATA

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Abstract

Compliance with today's regulatory requirements for safeguarding the public and environment, place significant importance on the validation of data collected for environmental monitoring, site characterization, and remedial response. Important decisions directing compliance and resolving existing environmental hazards must be based on data which are technically and legally defensible. A methodology has been developed at the Idaho National Engineering Laboratory (INEL) to ensure that data collected for the INEL Environmental Restoration Program (ERP) are defensible. Application of this methodology qualifies data by ensuring that: (a) reasonable and appropriate data collection requirements and objectives are established prior to field sampling; (b) proper field sampling techniques and procedures are established and followed; (c) appropriate sample analysis methods, procedures and quality assurance and control are used; (d) data qualitative and quantitative statements for the data are established and associated data uncertainties assigned; and (e) results are independently reviewed to verify documentation, data, processes, and services conform to specification requirements. This paper summarizes the methodology developed for qualification of radiological and hazardous waste data collected for the ERP at the INEL.

INTRODUCTION

The INEL is a government-owned, contractor-operated facility managed by the Idaho Operations Office of the U. S. Department of Energy (DOE-ID). EG&G Idaho, Inc. is the prime contractor that operates many of the facilities at the INEL. In July 1987, DOE-ID, Region X of the Environmental Protection Agency (EPA), and the U. S. Geological Survey (USGS) entered into a Consent Order and Compliance Agreement (COCA) to address past waste management sites at the INEL. Many of the waste management sites are composed of mixed waste, a mixture of both hazardous and radioactive waste. Most of the sampling techniques require obtaining samples for both hazardous and radioactive analysis. Even though different analytical methods are used for hazardous and radioactive samples, the same general methodology applies for validation of the data obtained from the results.

Decisions must be based on validated data with known uncertainties. This is not only good engineering practice but in the realm of environmental compliance it is required to ensure that data are technically and legally defensible. Good data does *not just* happen it is the product of good planning, the application of appropriate procedures, documentation, and validation. The data validation process provides documented confirmation of the adequacy (suitability for its intended purpose) of the data reviewed. Through this process invalid data are identified and the usability of the remaining data are qualified.

The methodology for qualification of data within the ERP at the INEL includes five phases which encompass pre-sampling planning, sampling, laboratory analysis, data analysis, and independent technical review. After the qualification process is complete, the data are placed in a controlled database and backed up with a documentation file.

General Methodology

The methodology for qualification of data for the Environmental Restoration Program at the INEL can be summarized in five consecutive phases: (a) pre-sampling; (b) sampling; (c) laboratory analysis; (d) data analysis; and (e) independent technical review. Fig.1. illustrates the qualification process for radiological and hazardous waste data. A description of the activities within the phases of this methodology is given in the following subsections.

Pre-Sampling (Phase 1)

Before any sampling begins, proper planning should be performed to assure that the requirements are defined and can be met. A key activity of the pre-sampling and planning phase is to establish Data Quality Objectives (DQOs) (1). DQOs are qualitative and quantitative statements which specify the quality of the data required to support decisions and are determined based on the end uses of the data to be collected. DQOs are established for all sampling tasks and provide the guidelines for data validation and independent

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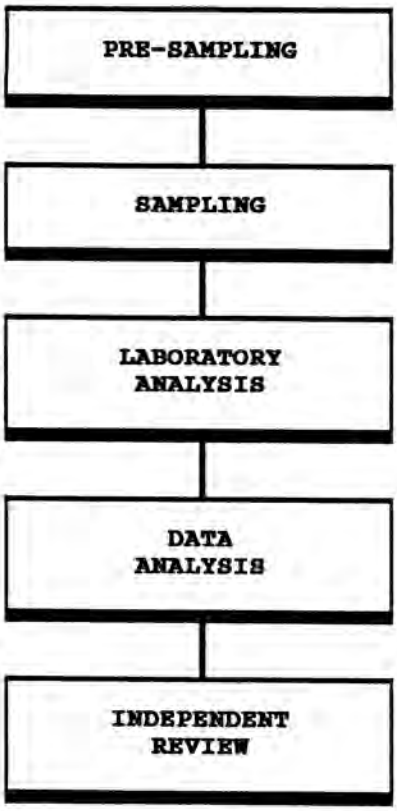

Fig. 1. Methodology for Qualification of Radiological and Hazardous Waste Data.

technical reviews. Following establishment of DQOs, they are included in a Sample and Analysis Plan (SAP) which is written for all field activities. The SAP contains: (a) a quality assurance project plan that describes the policy, organization, functional activities, and quality assurance and quality control protocols necessary to achieve DQOs dictated by the intended use of the data; and (b) a field sampling plan that provides guidance for all fieldwork by defining in detail the sampling and data-gathering methods to be used on a project (2). Prior to field activities the SAP is given an independent technical review to identify deficiencies, inconsistencies and inefficiencies associated with the DQOs, data requirements, sampling and analysis methods and procedures, etc. Changes are incorporated and the SAP is then approved.

Sampling (Phase 2)

Evaluation for compliance with sampling procedures and evaluating field logs are part of the methodology performed during the sampling phase. Where practical a quality assurance field audit should be performed. Evaluation of rinsate and contamination control is also part of this phase. It must be appreciated that the sampling collection is the most important part of the activity. If this phase fails then any resulting data will be greatly compromised, if not impossible to interpret. Field logs are carefully examined for any abnormal information that might compromise the data. It is important that proper procedures are identified and followed to ensure data integrity and traceability. Review of the field activities is part of the data validation process and proper documentation should be provided for review.

Laboratory Analysis (Phase 3)

If laboratory analysis is associated with the sampling then a review of the laboratory is required. The laboratory analysis begins prior to the sampling program. This initial step consists of a quality assurance audit to ascertain if the applicable procedures are in place to guarantee quality control during the laboratory analysis. If this audit is failed then the laboratory should not be used because the uncertainty will be in question.

The second step in the laboratory analysis is to verify that the uncertainty limits of the analysis are within those established. (These may be EPA historical uncertainties or those established by the laboratory.) This is established by analyzing method blanks, spikes, continuing calibrations and initial and final calibrations. If the data fail to meet any criteria then the uncertainty must be reevaluated and potentially increased.

In addition, laboratory performance requirements should be in place to assure that laboratory reporting formats and documentation are clearly established and specified to support data evaluation and validation.

Data Analysis (Phase 4)

In this phase data are evaluated and analyzed to document the adequacy (suitability for its intended purpose) of the work under review. Invalid data are identified and the usability of the remaining data are qualified. A data package is prepared to assist in this validation process. This package includes copies of the SAP, standard operating procedures, detailed operating procedures, logs, chain-of-custody shipping manifests, statements of work for laboratory analyses, and lab data packages.

The validation process consists of: (a) Verifying that the documentation is complete and traceability to establish procedures are maintained; (b) Performing a systematic analysis based on an established data validation methodology.

Verifying that the documentation requirements are satisfied establishes the basis for *the uncertainty* limits. Calibration information for field instruments, field logs, field audits are all examined during this step. Completeness of chain-of-custody forms and compliance with procedures is also evaluated. Completing this step allows one to say that the uncertainty has not been compromised by field activi-

ties. The verification of laboratory analysis is a product of activities performed during phase 3.

Next a systematic evaluation of the data is performed to check accuracy, precision, completeness, comparability, and representativeness. Redundancy checks are a significant part of this evaluation. These checks are divided into direct, historical, and analytical redundancy. Direct redundancy compares two or more identical data sets. Duplicates or splits are common examples of direct redundancy. To be satisfied, the data must fall within their uncertainty limits as established in the DQOs. Historical redundancy compares the same data form with different sampling activities, i.e., time. Again the data sets must be within their uncertainties. The last redundancy check is analytical redundancy. In this analysis, data are compared to models or statistical fits of comparable data, etc. An example of this would be performing a least squares fit for samples at various elevations in a well or locations in a pond. The data being evaluated must fall within the uncertainty limits of the least squares fit. Analytical redundancy must be used with caution, in the environmental world, due to heterogeneity of the phenomena. If the data satisfy the criteria it is probably correct but non-conformance is not an explicit indication of bad data.

Independent Technical Review (Phase 5)

This phase consists of an independent technical review of the analysis from phases 3 and 4. The results from the data validation process are submitted to an independent review committee to perform a verification. The verification process is an audit function and is performed on a selected subset of the validated data and support documentation to verify the usability of the data is correct. The review committee consists of individuals with appropriate technical competence and who; had no direct responsibility for or involvement in performing the activity or work, are not accountable for the activity or work results, and do not report directly to the immediate supervisors who are responsible for performing the activity or work to be evaluated.

Data Base Entry

The final activity is to place the data in a controlled environment. Electronic data base entry is controlled by (a) logging all entries and (b) verifying that the entry is complete and accurate. Entries include the data with uncertainties plus all lab quality control data (continuing calibrations, spikes, laboratory method blanks, etc.). In addition to the electronic data base, all hard copy records are stored in the programs controlled documentation repository. This includes all originals such as chain-of-custody forms, field log books, SAPs, and any changes to procedures and all detailed operating procedures, field audits, laboratory documentation and all data integrity reviews. These data are maintained in the controlled documentation environment and only copies are released to authorized requestors.

CONCLUSIONS

Key decisions affecting the storage, control, and remediation of hazardous substances affecting the environment and public should be based on validated data and information. In order for these decisions to be technically effective, cost effective, and provide protection to the public health and environment they must be based on data with known qualities and uncertainty. Careful preliminary planning and a well established consistent data qualification methodology is the best approach and assurance against wasted field sampling efforts, duplication of efforts, and management and technical misdirection. Adherence to the methodology summarized in this paper will provide data which have the qualities necessary to meet decision requirements and are technically and legally defensible.

REFERENCES

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