TOTAL DATA QUALITY - THE TREND OF THE '90'S

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ABSTRACT

Data quality has become a very important issue for environmental activities at operating facilities and remedial investigations/activities. The Weldon Spring Site Remedial Action Project has developed a thorough program to assess and document data quality. This program includes the development of specific data quality objectives, detailed planning of sampling activities, performance of data verification and validation, and the implementation of a data management program.

The program developed at the Weldon Spring Site addresses all phases of data quality. The steps used in this "Total Data Quality" program can and should be used by other facilities relying on analytical data supplied by internal and external laboratories. The methods and processes can be customized to any program based on need and available resources.

INTRODUCTION

The impacts of data quality on waste management and remedial action are rapidly becoming a critical issue. The importance of this issue increases as evidence of poor quality analytical results surface and as the Environmental Protection Agency (EPA), the Department of Energy (DOE), state agencies, and the public closely scrutinize data related to waste management decisions and environmental surveillance activities.

The Weldon Spring Site Remedial Action Project (WSSRAP) has responded to the data quality challenge. The WSSRAP is the DOE's cleanup of an inactive uranium processing facility in eastern Missouri. The WSSRAP has dealt with issues related to data quality since 1988 and has developed a program which systematically reviews and evaluates data quality. The WSSRAP program ensures that data of known and documented quality are used in significant environmental decisions. This program has been developed in response to the requirements of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and DOE Order 5400.1.

ORIGIN AND STATEMENT OF THE PROBLEM

In the past, analytical results were often considered sacred. Results received from analytical laboratories were used for decision making without questioning the quality or validity of the analyses that generated those results. This often reflected a lack of understanding for the analytical methods used and the opportunities for introducing errors in data management at the analytical facility.

During the early 1980s, sampling methods, decontamination techniques, and other field practices were evaluated and improved in order to assure the samples were representative of actual conditions. The development of analytical methods also progressed as detection limits entered the part per trillion range. However, the documentation of data quality independent of laboratory review, lagged behind these other developments. As a result, the validity of many investigations may be questioned due to lack of an independent evaluation of data quality.

The unilateral success of Japan's quality efforts in the manufacturing arena during the 1970s made the need for improvement in American manufacturing evident and Total Quality Management (TQM) has slowly infused American corporations and management(1). TQM originated in the Federal Government in 1986 with the signing of Executive Order 12552. This order was designed to improve the quality and productivity of agencies in the executive branch by 1992(2). In part to meet the requirements of this executive order, the Environmental Protection Agency (EPA) began developing a structured approach to help achieve these goals in dealing with the nation's environmental problems. This approach was to produce standard methods and results for use in identifying environmental problems, developing regulations, and assuring compliance with the regulations(4). From this structured approach, improvements have been made. However, some problems have also developed which complicate environmental investigations.

Problems center primarily around efforts to apply all TQM principles to environmental investigations. These principles may apply to some aspects of these investigations, but the EPA appears to have connected TQM, which is designed to improve productivity and quality, to data quality. This connection was likely made because analytical costs are high in relation to other aspects of the investigative process. As a result of this connection, analytical data generated during the CERCLA process currently receives significant scrutiny. This scrutiny is usually justified given the importance of the decisions to be made based on the data (i.e. health risks, environmental impact, etc.). However, the lack of clear guidance from the EPA for evaluating data quality makes developing a defensible position difficult.

The EPA guidance for conducting remedial investigations and feasibility studies states that decisions should be

based on data of known quality and validity(5). Unfortunately, the EPA guidance documents do not explicitly state how one should implement modified aspects of TQM to data generated as a result of site characterization, routine effluent monitoring, and environmental surveillance activities.

Reports of unlawful and unethical practices by analytical laboratories have recently surfaced. These practices range from the fraudulent reporting of data to shortcutting analytical procedures. The impacts of these practices can affect the precision and accuracy of results or render data totally unusable. While the majority of analytical laboratories are operated in an ethical and technically sound manner, these reports cause the work of all laboratories, both good and bad, to be questioned.

THE SOLUTION - TOTAL DATA QUALITY

To solve the problems associated with this lack of clear guidance and to eliminate potential problems with analytical laboratories, the WSSRAP has developed a total data quality (TDQ) program. This program ties the separate guidance documents and objectives together in a manageable and well-defined program which results in environmental data of known quality. The intent of the EPA guidance documents has been addressed in the development of this program.

The WSSRAP TDQ program integrates the standard aspects (as detailed in EPA guidance documents) of data quality and the intent of the guidance with site-specific details to provide clear guidance and direction for the data collectors and decision makers. The WSSRAP TDQ program also eliminates blind reliance on laboratory performance by routinely evaluating the quality of the analyses performed.

ASPECTS OF TOTAL DATA QUALITY

The WSSRAP TDQ program consists of numerous initiatives within each aspect of data collection, evaluation, and reporting. A specific program level plan detailing all aspects of data collection and management has been prepared. The Environmental Data Administration Plan (EDAP) provides the foundation for collecting, reviewing, and interpreting data(6). The EDAP also provides site-specific guidance for all facets of managing data and the associated documentation and establishes general Data Quality Objectives (DQOs). This plan includes guidance on sampling plan preparation, data verification, data validation, database administration, and data archival.

These initiatives and related guidance are described in further detail in the following paragraphs. Figure 1 presents the aspects of the WSSRAP's TDQ program.

Planning

All WSSRAP sample collection activities are documented in detailed sampling plans that indicate sampling methods, locations, rationale, and quality control measures. Sampling plans are prepared for all environmental sampling events. DQOs are also reviewed for each investigation and revised if necessary.

Data Quality Objectives

The EPA guidance for conducting Remedial Investigations and Feasibility Studies states that project specific DQOs should specify whether data is valid with qualifiers. The guidance also recommends that DQOs state which qualifiers can invalidate data(5). EPA guidance for DQO development requires that the data manager: (1) outline the DQO development process, (2) identify decisions based on data at various stages of the RI/FS, (3) identify and define data uses and needs, and (4) outline the design of data collection activities(7).

The guidance states that establishing universal goals for precision, accuracy, representativeness, comparability, and completeness (PARCC) is not practical. Specific guidance for establishing goals for PARCC is not provided although historically achievable precision and accuracy levels are provided. A one-page form is used to document the development of DQOs. This form is not conducive to the development of detailed objectives.

The guidance also states that judgement should be used by the data user with appropriate technical expertise. Unfortunately, few people truly have the required expertise to interpret and evaluate the quality of analytical results.

To overcome problems associated with the lack of definitive guidance, the WSSRAP has developed detailed data quality objectives for all analytical parameters and media. Specific goals for the precision and accuracy of analytical data have been established for all environmental media sampled at the WSSRAP. The representativeness of the overall sampling program is evaluated by a subprogram used to collect samples specifically for this purpose. Data comparability is established by using standard analytical methods. The completeness goal for WSSRAP data has generally been established at 85 percent. The DQO development process is presented in Fig. 1. To assure that DQOs remain current with technology advances, the precision and accuracy of analytical methods is reviewed annually and revised as appropriate.

Sampling

Site specific procedures have been developed for all aspects of sample collection and handling. These procedures were developed from the EPA and other relevant guidance documents and are reviewed annually and revised

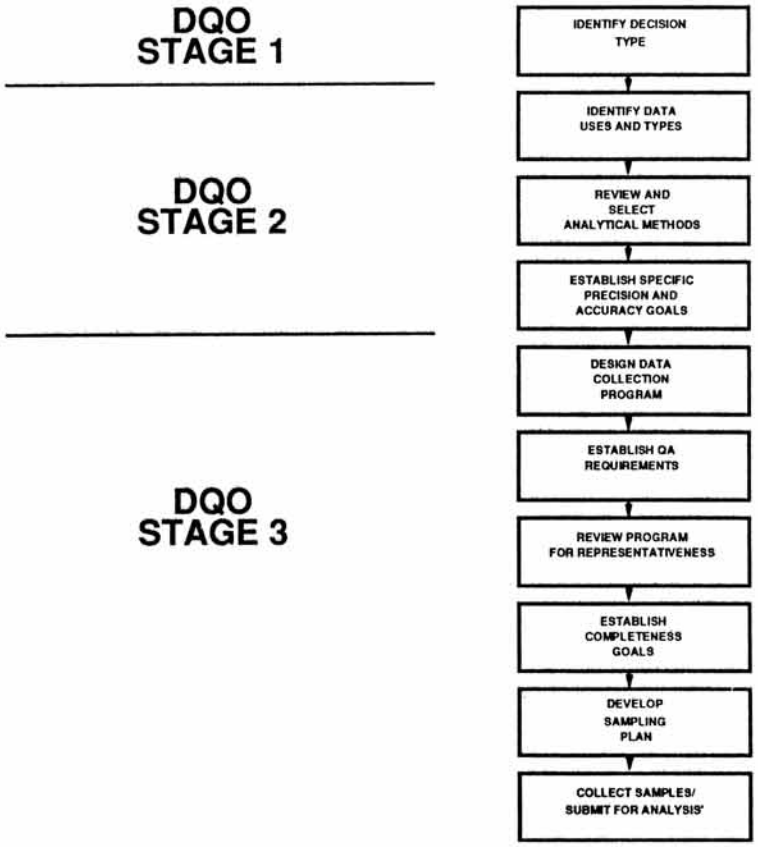

Fig. 1. DQO development process.

as necessary. Procedure training is provided to sampling personnel prior to sample collection. All procedure training is documented and tracked so that personnel are retrained as procedures are revised.

All samples are collected by using the specific sampling plans prepared for each investigation. Variances or field modifications are noted in field notebooks and on sampling forms.

Quality assurance samples are collected to assess location variability, the effects of sample matrix on analytical procedures, and the effects of sampling methods and shipping on analytical results. Chain of custody is maintained for all samples from collection through shipment to the analytical laboratory.

Laboratory Analyses

Problems and/or uncertainties may also be introduced during laboratory analysis of samples. Unless significant precautions are taken, the impact of these problems or uncertainties may not be detected.

Laboratories analyzing the WSSRAP samples are required to develop project-specific quality assurance project plans (QAPjP) which detail the preparation and analyses of samples. These QAPjPs are reviewed and approved by the project's quality assurance personnel prior to commencement of analyses. Laboratories are also required to comply with standardized reporting requirements, thus simplifying data verification, validation, and interpretation.

Laboratories are audited to assure compliance with the QAPjPs and detailed analytical procedures.

Data Verification

All data received from analytical laboratories is subjected to data verification. The data verification process is presented in Fig. 2 and consists of a preliminary review of the quality impacting aspects of sampling, analysis, and reporting. Data verification includes reviewing field sampling documentation, sample preservation, chain of custody, analytical holding times, and a comparison of electronic versus hardcopy reporting.

Data verification assures that all data is received for every sample submitted for analyses and includes a preliminary review by the data users. Electronic and hardcopy results are compared to assure that errors were not made during data entry. The verification process also assures that any noted discrepancies and the resultant changes are documented. This assures the data users that, regardless of format, the results are correct.

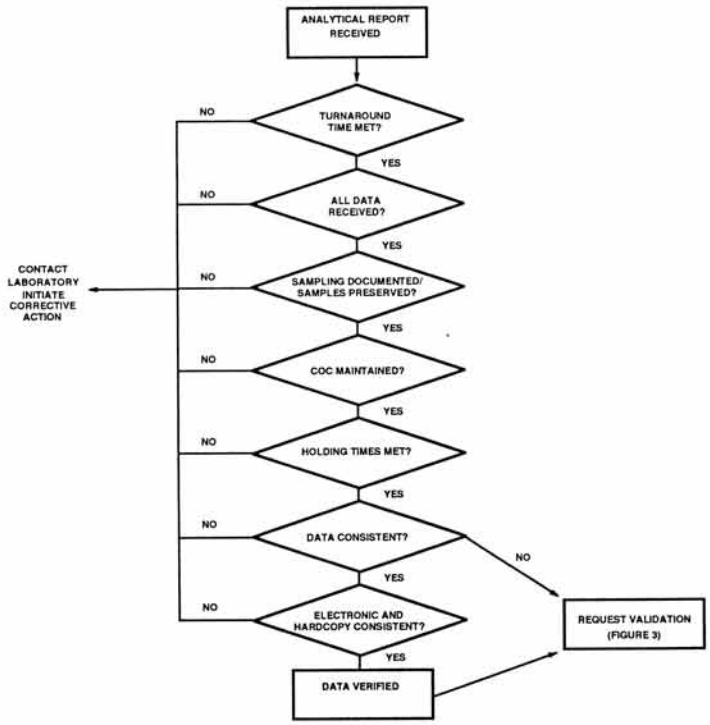

Fig. 2. Data verification.

Data Validation

Data validation is performed independent of the analytical laboratory. This process reduces the possibility of data users blindly accepting laboratory results as valid and establishes a defensible position when data are scrutinized.

Data validation consists of two primary functions. First, the analytical process is reviewed and the quality of the data is documented. This consists of reviewing all records related to sample integrity, sample preparation, and the analytical measurement systems. Second, the data is compared to the method-specific criteria and site-specific data quality objectives. This ensures that data quality is evaluated based on the end use of the data.

At the WSSRAP, approximately 10% of all analytical data is validated according to site-specific procedures. Approximately 5% is evaluated on a random basis to provide coverage across all data sets. The other 5% is selected from critical data. The 10% validation actually reviews a large portion of the analytical lots, effectively validating a much larger percentage of the data base. This is accomplished by reviewing information affecting quality such as instrument calibration which is the same for all samples in an analytical lot.

A comprehensive understanding of the analytical processes and methods employed is required to validate analytical results. The useability of the data is established by validation. The final step involves comparing results to the method criteria and data quality objectives. Qualifiers are attached to data records that have been validated. This allows data users to assess the quality of the data being used without requiring a detailed knowledge of the analytical processes. The data validation process is presented in Fig. 3.

Data Management

Data management at the WSSRAP is performed according to site specific plans and procedures. Data at the WSSRAP is available to users in both electronic and hardcopy format. Electronic data is accessed by site-developed data management software. Formal records are also placed in secured storage and access to the database is restricted to assure that no unauthorized editing is performed.

SUMMARY

A significant commitment to data quality has been made at the WSSRAP. This results from an increased awareness of how important data quality is to the success of the project and to the fulfillment of obligations to the regulatory community and the public. The program developed for this remedial action project may be applicable to other environmental projects, both large and small. Implementation of a total data quality program is not a simple task, but it is a worthwhile investment in the successful completion of environmental projects.

By using the guidance provided by the regulatory agencies and the lessons learned at the WSSRAP, a sound total

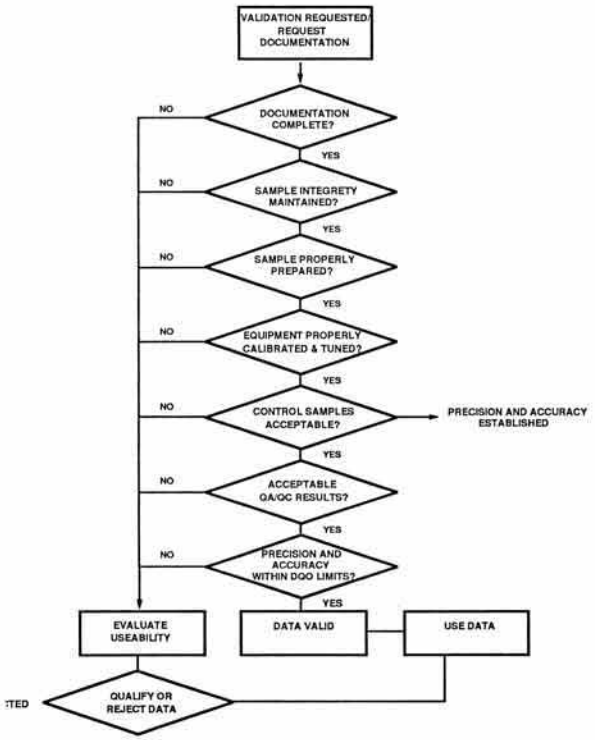

Fig. 3. Validation request.

data quality program can be developed. Historical data can be evaluated, although the program will be more efficient if data quality is assessed as it is gathered. Program needs and personnel requirements will vary, but the investment in documenting data quality is small when compared to the impact of delaying a project while data quality is evaluated.

ACKNOWLEDGEMENTS

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