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QUALITY DATA VALIDATION

COMPREHENSIVE APPROACH TO ENVIRONMENTAL DATA VALIDATION

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Environmental data validation or evaluation consists of an assessment of three major areas inherent to the achievement of overall data quality and usability. These major components are:

- analytical method validation;
- field procedures and documentation review; and
- an evaluation of the level of achievement of data quality objectives based in part on PARCC parameters analysis and expected applications of the data.

The PARCC parameters are precision, accuracy, representativeness, completeness, and comparability. In the realm of CERCLA activities, the data quality objectives are strictly tied to the identified expected use of the data. Although analytical validation of environmental data at particular levels of validation result in a PARCC-directed measure of data quality, the comprehensive evaluation of the level of achievement of "project" DQOs is only possible after evaluations of the adherence to field sampling procedures and documentation requirements surrounding the sample collections which initiated the process of the generation of environmental data.

A program utilizing matrix associations of required levels of validation effort and analytical levels versus applications of this environmental data was developed in conjunction with DOE-ID guidance documents to implement actions under the Federal Facilities Agreement and Consent Order in effect at the Idaho National Engineering Laboratory (INEL). This was a multi-contractor effort to bring consistent quality to the INEL-wide Environmental Restoration Program and database in an efficient and cost-effective manner. This program, which documents all phases of this review process, is now being expanded by individual contractors to other phases of environmental monitoring being conducted under DOE Order 5400.1.

I. Introduction

Environmental sample data is generated every second in the United States to support environmental projects or maintain interfaces between the operations aspects and the environmental regulations for industry, commercial

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entities, government owned facilities, etc. Applications of such data sets may include several of the following:

- determine applicability of environmental regulations,
- waste management decisions,
- transportation decisions for wastes,
- compliance with environmental regulations thresholds,
- determination of emissions,
- risk assessments,
- Remedial Investigations and Feasibility Studies,
- RCRA corrective action measures,
- design of remedial action systems,
- monitoring of remedial action systems performance, and
- certification of achievement of cleanup goals.

The validity of such data is a function of the design and implementation of the project's or program's quality assurance(QA) and quality controls(QC) relating to sample collections, sample receipt and storage of samples prior to the performance of analyses, and, finally, the performance of the analyses and associated data reductions and data reporting. The guidance and/or requirements for what constitutes acceptable QA/QC for the environmental data for specific projects originates with the "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAMS-005/80", as issued by the Quality Assurance Management Staff of the U.S. EPA(EPA) Office of Research and Development, method-specific and EPA program guidance documents such as the "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846" and the EPA Contract Laboratory Program(CLP) Users Guide, 40 CFR, as well as applicable field sampling plans(FSP), waste analysis plans(WAP), and quality assurance project plans(QAPjP)..

2. Sample Verification

Comprehensive validation of environmental sample data first requires a sample verification process which relies heavily upon a comprehensive review of field documentation and logs (generated by samplers or automatic instrumentation), sample tracking forms, shipping documents, chain-of-custody(COC) forms, laboratory internal sample tracking logs, sample preparation logs, laboratory data sheets, and the final reports of analytical results as issued by the analyzing laboratory. This sample verification process verifies that the analytical results for each sample are able to be traced back to specific samples and sample locations. Usually the laboratory performs a check of the internal sample tracking documentation as part of it's internal QA Program implementation of routine data reviews before issuance of final reports. Contractual arrangements usually need to be made via project procurement entities representing project management and the data users if the laboratory is expected to provide either a complete validation service or extensive documentation in support of an independent data validation.

Also inherent to this verification phase of the validation process is

the need to verify physical sample security and legal defensibility of the resultant data for project samples from the point of collection to the point of analysis. Prior to shipment and after receipt by the laboratory, use of secured area sample storage and strict adherence to COC procedures, including the use of chain-of-custody seals, should achieve the required sample security. Documentation of such compliance during field activities should be readily available for the validator's review.

A check by the validator for the documentation of the use of COC seals on the shipping containers (often coolers) for the sample shipments will verify that the samples were not tampered with or otherwise altered in anyway during shipment. Often the use of individual sample seals further guarantees that the samples are not tampered with after collection. A check of the laboratory sample receipt and log-in records should verify if the samples were received with all sample and shipping container seals intact, and whether or not preservation temperatures were sufficiently maintained whenever the requested analyses required cooling of the samples between collection and analysis.

3. Data Reductions Check

A thorough review of the calculations and data reductions, as performed by the laboratory's analysts to arrive at the final reported analytical results for the project samples, is an integral portion of any review or validation of the reported environmental sample data. For many laboratories this internal review is accomplished for a percentage of the project samples. Other laboratories with more stringent quality assurance requirements, such as labs in the CLP Program, may review 100% of their data and calculations. In the laboratory reviews, typically supervisory chemists or analysts who did not perform the given sample analyses perform an independent check of the data sheets and the calculations of the analyst, looking for transcription or mathematical errors. Once this function has been accomplished and the associated sample quality controls for the method have been reviewed, the analytical results will either be qualified, approved without qualifications or rejected as appropriate.

The review of the analytical laboratories calculations and data reductions, performed as one part of a more comprehensive and independent validation of the analytical data generated by an environmental project or program, is a redundant check of these same laboratory documents. The validator looks for transcription errors, computer input errors, and errors in mathematical calculations. The performance of this portion of the validation requires the validator to secure and review data sheets, worksheets, logbooks, instrument print-outs (eg., strip-chart recorders, chromatograms, integrator outputs), laboratory information management system (LIMS) outputs, and final reports.

The validator must verify the validity of the calculations and data reductions which yielded each analytical result based on the quantitative effects of the preparation and method procedures, the weight or volume of the sample which was initially prepared for the analysis, and any dilutions or concentrations required for the final matrix for the sample as placed into the

analytical instrument. A more in-depth review of the efficacy of the weights, volumes, dilutions, etc. used by the analyst(s) is a function of the method validation which considers required procedural steps and method QC.

Again contractual arrangements usually need to be made by project management representing the data users if the laboratory is expected to provide an independent validator with the extensive documentation and raw data required to perform a review of all calculations and data reductions for your environmental project or program. Laboratories already participating in stringent programs such as the CLP will be well versed in providing such detailed data packages.

4. Analytical Method Validation

The performance of the method validation portion of the validation of environmental project data is typically accomplished for each individual sample delivery groups (SDG). A SDG is defined as whichever occurs first:

- each Case of field samples; or,
- each twenty field samples within a Case; or
- each 14 calendar day period during which field samples in a Case are received, beginning with the receipt of the first sample in the SDG.¹

A Case is a logical grouping of a project's samples from one or more sample delivery groups for which the laboratory issues a narrative report to project management detailing observed problems with analytical or field QA/QC, documentation, sample matrix effects, insufficient sample volumes, unusual events, required reanalysis, or other corrective actions performed by the laboratory. Since all samples analyzed from within one SDG may be readily associated with a limited number of QC samples analyzed in a restricted period of time in the lab, the analytical results for each SDG constitutes the logical unit of information to be reviewed for the method validation portion of environmental project data validation. However, from the laboratory's perspective, the Case is the most cost-effective level for the organization of final reports or reports of internal data reviews.

Therefore, Case Narratives are the logical means of conveying the particular problems encountered in the analysis of project samples to appropriate project management and data users. Analytical methods as defined in EPA guidance documents are classified into five analytical levels (I, II, III, IV, & V)². Analytical level I is comprised of various field level parameter screening methods and direct read-out environmental monitoring which require various degrees of implementation of standard operating procedures (SOPs) such as calibrations and/or check standards, but typically not requiring extensive QC documentation. Level I field methods typically give real time measurement of results which field samplers are required to record on appropriate sampling information sheets or logs as specified by the project sampling and/or work plans.

Validators should review all necessary project field documentation to

establish that field screening parameters for samples of various environmental media were properly measured and documented. The validation includes checks for adherence to field instrument SOPs, instrument calibration and maintenance SOPs, as well as to any required QC associated with the applications of these instruments.³

Analytical methods belonging to analytical level II are methods which, although they are standard or modified standard methods using relatively complex analytical instrumentation, are implemented on-site.² Often field labs are mobilized in transportable trailers and used to analyze site environmental samples by analytical level II methods. The extent and types of required QC and the resultant documentation generated by level II analyses will vary with the analytical methods and standard operating procedures required by the project plans. Typical instrumentation utilized in field labs could include gas chromatographs, atomic absorption spectrophotometers, flash point testers, total organic carbon (TOC) analyzers, and total organic halogen (TOX) analyzers. As appropriate to the method, information available to the validator for review should include data sheets, analyst worksheets, integrator or strip chart recorder print-outs, chromatograms, and log books pertaining to standard preparations, sample preparations, analytical runs, and instrument maintenance and calibrations.

Analytical level III methods are standard EPA-approved methods performed off-site, typically by commercial laboratories certified in the particular programs to which project sample results are to be applied.² Level III protocols, being associated with only EPA-approved standard methods, have a multitude of inherent requirements for analytical QA/QC which may include both initial and continuing calibration standards, surrogate spikes, analysis of various blanks, reference samples, instrument performance samples, internal standards, laboratory control samples, precision and accuracy requirements, etc. In addition, associated EPA Statements of Work (SOW), such as for the CLP Program, and guidance documents such as SW-846 may apply to analytical level III methods used for specific projects. These additional requirements include QA/QC such as trip blanks, field blanks, replicate or duplicate field samples, matrix spike and/or duplicate matrix spike samples (MS/MSD), and blind sample controls to be analyzed along with project samples. Implementation of these programmatic requirements at the project level is typically realized by specifying this additional associated QA/QC within the field sampling plan or waste analysis plan as applicable. These level III methods include available information regarding the precision and accuracy which has been demonstrated as achievable based on results for the analysis of a given matrix by several certified labs participating in controlled parallel analysis studies of the method performance. Often the matrix used to generate this window of achievable precision and accuracy for the method is aqueous or a "simple" soil or a surrogate soil. The reality for matrices found in contaminated sites is that such soils are much less amenable to yielding predictable method performance due to the presence of various interfering contaminants or to the physico-chemical characteristics inherent to the particular matrix structure itself.

It is the duty of the validator to review the achieved precision and

accuracy of the analytical results for analytical level III methods against the particular method's requirements and against any special requirements specified in the project sampling plan or QAPjP. Typically a regulating agency will not approve project plans which specify precision and accuracy goals which are less stringent than the method criteria unless there is existing data which substantiates that the matrix to be sampled presents analytical difficulties as outlined above. In addition to this review of precision and accuracy, the validator will review the achieved completeness for the sampling and analysis of each applicable analytical parameter for all sample locations against originally scheduled project goals for completeness as specified in project plans. Technically, completeness is that percentage of scheduled project samples for which reported analytical results were "acceptable" based on QA/QC criteria specified by the analytical methods and the project plans.⁴

Another key item for the validator to check is sample holding times for each analytical method utilized for project samples. It must be verified whether or not the time elapsed from sample collection until the time of sample analysis exceeded the maximum holding time allowed by each analytical method. The COC form as well as lab internal tracking documents need to be reviewed. The holding times for standard EPA methods and programs are well-known to commercial environmental laboratories.

The programmatic technical requirements for sample holding times have only been established for water matrices, and may be found in 40 CFR 136. However, several EPA Regions have established general technical holding times for various classes of analyses and sample media. Several EPA-approved methods which require extraction procedures before analysis have holding times for both the time until extraction and the time until analysis. Care should be taken to distinguish between contractual and technical requirements, since the contractual holding times are typically from the verified time of sample receipt (VTSR) at the laboratory, while technical holding times are from the time of sample collection. Exceeding the method-required technical holding times will generally cause rejection of analytical results, particularly where a regulatory threshold is involved.⁵

Other commonly accepted criteria for evaluating the quality of environmental sample analytical results are the representativeness and the comparability of the data. These parameters (precision, accuracy, representativeness, completeness, and comparability), when considered together, are assigned the acronym PARCC. The criteria of representativeness and comparability are qualitative in nature and are evaluated by consideration of various aspects of the sampling and analysis processes.

Comparability may be evaluated by reviewing the level of adherence to such project requirements or guidance as project SOPs, the analytical method requirements, and the precision and accuracy goals for the project's analytical data. For example, if review of the field procedures documented in the field logbook for a round of groundwater sampling indicates that a particular well was not purged for the requisite three well volumes before sampling, that sampling round will produce analytical results which have poor comparability

to those results from the rounds where the purge procedures were correct.

Representativeness is the degree to which sample data accurately and precisely represent a characteristic of a population, variations of a parameter at a sampling point, or an environmental condition. Representativeness may be evaluated by the validator's review of sample results for collocated (duplicate) samples for achieved field or overall precision, by review of the results for matrix spike and matrix spike duplicate samples, by review of sampling procedures and locations as implemented in the field for compliance with project plan requirements, and by statistical treatments of sample data to quantitatively estimate field and laboratory method error levels.

Performance of a thorough review of the analytical results for the various project blanks by the validator is very helpful in evaluating such parameters as comparability, representativeness and accuracy from the perspective of identification of contaminants introduced into the samples either between the time of collection and the time of analysis, or as a result of inadequate decontamination procedures used for sampling equipment during field activities.

EPA analytical level IV methods, also known as Routine Analytical Services (RAS), as well as analytical level V or Special Analytical Services (SAS) which are approved for case-by-case analytical situations, are more controlled in the requirements for documentation of QA/QC by the laboratory as well as for the data package deliverables and the reporting format for analytical results for both project samples and supporting QA/QC samples. EPA analytical Level IV methods must comply with the guidance in the CLP users guide which specifies extensive requirements for QA/QC, analytical instrumentation, documentation in both the field and laboratory, SOPs, and data package deliverables.³ Although developed to guide the performance of laboratories participating in the analysis of samples from sites associated with the "Comprehensive Environmental Reclamation, Compensation and Liability Act" (CERCLA), the CLP Statement of Work has become the standard for laboratories performing chemical analyses for a variety of clientele attempting to demonstrate compliance with various environmental regulations. Validators validating data resulting from analytical level IV methods must perform the most detailed validation procedures in order to establish the quality and useability of such data. Such validations also require that the validator have access to very comprehensive analytical data packages in addition to the project SAP, QAPjP or WAP.

5. Data Packages

Validators must have access to supporting analytical data packages where analytical level III, IV or V analyses are being validated. For analytical level III, the validator must be able to substantiate as part of the method validation that required analytical procedures were followed and that the method-required QA/QC criteria was adequate. However, in order to validate the analytical quality of data generated under the CLP guidance (analytical level IV), the validator must review very extensive data packages and also verify whether or not the documentation provided in these analytical data

packages substantiates that the laboratory's performance of each analysis was adequate when compared with the additional criteria contained in the CLP Statement of Work. For those data users securing level IV analytical services from CLP laboratories, but who are not accessing these services via the Superfund Program and the EPA Sample Management Office (SMO), the contract compliance screening segments of the validation process may not apply. This may allow for supporting data packages which are somewhat more streamlined than the RAS CLP data packages.

For volatile organic compound (VOC) analyses, these data packages are composed of a Case Narrative, traffic reports, QC summaries which include surrogate recovery information, method blank results, GC/MS "tuning" and mass calibration (actually an instrument performance using bromofluorobenzene (BFB), internal standards results, sample results, tentatively identified compounds, mass spectra results, reconstructed total ion chromatograms (normalized to the matched peak for the largest non-solvent compound peak in the printout), copies of raw spectra, reconstructed ion chromatograms and reports for the standards used in the initial calibrations and for standards used in continuing calibrations, raw QC data including: BFB "tuning"/performance spectra and mass listings, results and spectra for matrix spikes, matrix spike duplicates and for TICs detected in the samples. GC/MS library searches with spectra included are also required for TICs. All copies of raw spectra and mass spectra must be extensively labelled with sample number, lab file ID, date and time of analysis, GC/MS instrument ID, and compound names must be clearly marked on all spectra.¹ It is obvious from this example that an appreciable portion of the required validation time for analytical data generated under level IV analyses is consumed in the CLP requirements validation.

6. Data Qualification

The "Laboratory Data Validation Functional Guidelines for Evaluating Inorganic Analyses" (7/88), the "Laboratory Data Validation Functional Guidelines for Evaluating Organic Analyses" (2/88), the "Quality Assurance/Quality Control Guidance for Removal Actions" (4/90), and various other EPA-issued guidance documents specific to program areas of CERCLA present systems for data validation, complete with data qualifiers which are to be physically applied to data to identify limitations of the data or the rejection of the data based on technical considerations of the associated QA/QC. Initially, the laboratory supervisory and QA management personnel review all documentation and analytical results for the project samples and associated QC samples and, as necessary, assign lab qualifiers to the reported analytical results for the project samples based on these reviews. However, the laboratory may not in all cases know which field samples are associated QC samples or what the frequency of required QC samples is for the project or for specific sample delivery groups.

The independent validation which follows the laboratory's review of the project's analytical results, must consider any such additional information which references additional project designed quality controls. This independent validation will consider project data quality objectives, any programmatic data qualification guidance (eg., the "Quality Assurance/Quality Control Guidance for Removal Actions"), and additional PARCC or other

QA/QC requirements specified in project plans.

The end result of this process is the assignment of data user qualifiers or "flags" to the data along with issuance of a text report conveying the limitations, useability and validity of the reported project data, and, in some cases, the rejection of specific data which did not meet applicable minimum technical requirements or criteria contained in the analytical method, SAP or WAP, and/or statement(s) of work.

7. Field Quality Control and Documentation

All non-automated environmental sampling programs which involve the collection and analysis of discrete samples in connection with the mandates of environmental regulations should be guided either by a FSP or a WAP. The WAP applies to the operations of permitted treatment, storage and disposal facilities (TSDFs). Waste analysis plans, and often field sampling plans, are required to be submitted to and approved by the appropriate agency of authority (state agency or EPA). These field-oriented plans present the field level project-specific approaches to the sampling strategy as well as to the implementation factors such as documentation, procedures and required field QC sampling to support the project with samples which are potentially capable of yielding data adequate to meet the project's DQOs and overall QAPjP requirements for QA/QC for project sample data at each utilized analytical level (EPA levels I, II, III, IV, & V). Validators must review all available documentation generated in the field during sample collections in order to substantiate whether or not the procedures specified in applicable project plans, particularly the sampling plan and QAPjP, were adequately implemented during sample collections, sample preparations, and sample packaging and shipment.

Since any sample collection begins with a sample container, it is logical that validation of sample results should begin with a review of the quality of the container used to collect the sample. Documentation should be available demonstrating that the supplier either followed the recommended cleaning procedures pertinent to the containers for each analytical parameter or that the containers as provided by the vendor are approved as "EPA series" containers for the applicable analyses. Copies of the certificates of analysis for the containers, as originally supplied along with the containers by the vendor must be reviewed. Lot numbers on the certificates of analysis need to be compared to field documentation of the lot numbers of sample containers indicated as used during the sampling event. Likewise, the validator should check to see if duplicate samples for a parameter were collected in containers from the same lot, and to see if attempts were made in general to minimize the number of sources of containers as well as the use of containers from different lots.

Another approach which may have been required by the project plans (SAP, FSP, QAPjP, etc.) is the requirement of analysis of "bottle or container blanks" to determine container quality. The validator would review these analytical results to ascertain if any qualification or limitations of the useability of the analytical data is required based either on contamination detected in the container blanks or on failure to analyze the container blanks

with the required frequency for all pertinent lot groupings. Storage procedures used for containers in the field prior to use can greatly impact the quality of the containers. Since containers often arrive from the vendor with loose container lids, the procedures followed with sample containers on receipt and during field storage can either minimize or increase the potential for field-induced contamination before sample collections ever begin. At large RIFS sites, it is not unusual for sample containers to be staged at the site for weeks or months before use. The validator should check available field logs, certificates of analyses, COC forms, and sample tracking or traffic management forms to evaluate if container quality was properly addressed during storage as well as during sampling.

Sample collection methods and locations are the next logical topics in validating the methods and procedures used during sample collection. The validator must compare the field logs, chain-of-custody forms, returned sample tags and any sample tracking forms against the project guidance documents. This is an additional step beyond the sample verification process in that the adherence of the sample locations and methods used in the implemented sampling to the requirements of the project documents is evaluated. Aspects of these evaluations, as they apply to project DQOs, are discussed in Section Eight.

The next item of consideration for the validator is documentation of sample handling, preservations, packaging and shipping. The validator should verify the proper implementation of COC procedures, including proper completions of COC forms with signed, timed and dated surrenders and acceptances of custody for all phases of sample management. Type and size of sample containers used for each sample parameter should be recorded on the COC form. Preservations are often recorded on the COC forms and/or field logs and appear on the sample tags when tags are utilized. Once again, sample tag return by the laboratory may be requested and, when provided to the validators, serves as an additional validation tool in combination with sample tracking forms and COC forms. The validator, by checking comments on COC forms, by reviewing the Case Narrative from the laboratory, or by reviewing analytical reports will establish whether any samples were noted as improperly preserved, and thus may require rejection or qualification of those particular associated analytical results.

The final phase of field validation to be discussed is the review of field QC samples required in connection with project sample analyses. For field screening analyses, the documentation of field instrument calibration, operations and maintenance is reviewed against any requirements specified in the field sampling plan. The required QC for field screening parameters may vary greatly by project, but is generally not as rigorous as that for samples sent to the laboratory for analysis. The field sampling plan and/or QAPjP will directly address which analytical methods require the collection of field QC samples and the frequency of "collections" of such QC samples. Field QC samples include field blanks, trip blanks, equipment rinseate blanks, duplicate samples, split samples, blind QC check samples, and MS/MSD samples. The validator should verify through available documentation if the proper collection methods pertinent to each QC sample were followed. For example, MS/MSD sample aliquots may be collected and directly identified as such in the

field, but spiking of samples is generally discouraged as a field level activity per EPA recommendations. Also, for the analyses of water samples, several analytical methods absolutely require the collection of triple volumes of sample media in order to perform the MS/MSD. Field blanks should typically be identified as such for data qualification applications at the lab, while field duplicates may or may not be identified as such. Evaluation of the results for field duplicates should be interpreted on the basis of sample matrix. For example, the allowed precision range for water samples for the analytical parameter may be 20%, while the allowable range of precision for the results for the same parameter in soil could be 35%.

When qualifying data based on field QC the validator should also review all method-required QC to fully characterize and authenticate the cause(s) of the assignment of data qualifiers. If the laboratory missed the assignment of a required qualifier associated with improper calibration of the instrument, this would take precedence over consideration of minor contamination detected in one of the field blanks. Although statements of work exist for qualifying data under most CERCLA programs, these will never cover every decisional situation, may be argued as not applicable to the same analyses supporting other non-CERCLA environmental programs, and can never completely eliminate the use of professional judgement in given situations. Therefore, it is imperative to have validators who are experienced chemists who can evaluate the technical impact of both field-level and method-level deviations from the requirements of project plans, analytical methods, and regulatory agency guidance documents.

8. Data Quality Objectives

Data quality objectives (DQOs) are qualitative and quantitative statements and considerations which specify the quality of the data required to support project decisions or activities.⁸ During project planning, the DQO development process results in well-developed sampling plans, work plans and QAPjPs which detail the chosen sampling and analysis options and the required confidence levels and goals for PARCC parameters. Although originating in the CERCLA program, this DQO process is a programmatic evolution of the QA/QC considerations which EPA presented in SW-846 guidance applicable to all environmental sampling and analysis projects. Originally, the SW-846 made reference to "data objectives", but the 1990 Revision One of this guidance document uses the strict terminology of "data quality objectives" as previously implemented in CERCLA guidance documents.

Careful development processes for the project DQOs must be a cooperative effort between the project data users, project management and the QA management/oversight for the project. Once in place, the strict implementation of the project plans and the securing of a reliable laboratory should yield project data which is technically and legally defensible. This will maximize the likelihood that the data validators will be able to validate the analytical data, while minimizing the likelihood of assignment of limitations to data useability or user qualifiers due to failure to meet all project PARCC parameter goals, due to further identification of failures to meet method QC acceptance criteria, or due to variations from method performance

requirements. Selection of a laboratory which participates in some of the nationally recognized audit and performance evaluation programs for laboratories (eg., EMSL/LV, CEAT, etc.) will minimize the potential for the independent validator to have to do additional assignments of data qualifiers (based on QC or other method deviations) which the laboratory review process should have addressed.

The focus of the validation effort for project analytical data generated under CERCLA programs is the validation of "critical" samples. Additional emphasis is given to the results for such identified project critical samples since these results necessarily have to be acceptable per project plans as well as 100% validated in order for the associated project environmental management decisions to be made based on these analytical results. The project goals for the PARCC parameters may be designed to be more rigorous for the critical samples, with the possibility of increased frequency requirements for field duplicates or other field QC samples. For example, in CERCLA applications the validator must establish whether or not the project's analytical results for critical samples yielded 100% completeness. Additional programmatic DQOs applicable to CERCLA programs may require the validators to statistically determine the confidence level, the power and the minimum detectable relative difference values for the analytical results for the potential contaminants of concern at each specified exposure area and for each pathway for the project samples and for associated background samples for the site(s).⁷

In order for the independent validator to perform those portions of the validation process which are pertinent to the evaluation of achievement of project DQOs, extensive cooperation between the validation entity and the project management must occur to guarantee that the validator has access to all appropriate project plans, field documents, project-specific and programmatic statements of work, etc. required to perform the evaluation of DQO achievement. In some instances, the reality of the implementation of the review of DQO achievement is that this portion of the data validation process is often split between an external validator and "internal" QA oversight. For the internal approach, the QA oversight will probably have extensive access to project plans and enhanced knowledge of the project requirements while remaining independent of direct involvement with project operations and management. This approach minimizes the amount of documents which need to be externally disseminated, while still achieving a significant degree of independence for the overall validation process and realizing additional cost-effectiveness.

Whether or not multiple entities are involved in the actual performance of the validation process, reports detailing data useability and limitations should be generated by each involved validation entity. In addition to the obvious DQOs already discussed, validators should review the achieved detection limits for each analyte in each media sampled against those detection limits specified in the analytical statements of work for the project and the applicable SAP or WAP.

9. Idaho National Engineering Laboratory Contractor Program

The U.S. Department of Energy (DOE) has comprehensive programs in place which guide the environmental sampling and analyses at its facilities in support of the self-mandated 4700 Series of DOE Orders for environmental monitoring to protect the general public and ecosystems, in support of monitoring various emissions from its plants and TSDFs in compliance with applicable regulations, in support of permit-required environmental monitoring, and to support the implementation of its Environmental Restoration Program at each facility. The DOE has been active in the development of program technical guidance for the implementation of QA/QC requirements for the collection, analysis and subsequent validation of analytical results for environmental samples associated with the evolving Environmental Restoration and Waste Management Programs which guide such projects at various facilities and sites across the DOE complex. These DOE program guidance documents, while generally adopting the use of standard EPA methods and requirements, have to address the additional concerns for the potential for exposure of sample collection teams, analysts and even instrumentation to the effects of radiological contaminants. For DOE sampling teams, the "As Low As Reasonably Achievable" (ALARA) program requirements and controls must be satisfied to minimize the potential for any adverse health effects which could be associated with the collection and handling of the samples.

Shipments of samples to analytical laboratories must be screened and/or subjected to in-house radiological analyses before leaving the facility in order to protect site staff and the public, as well as to avoid either violations of Department of Transportation regulations or causing the analytical laboratory to exceed its Nuclear Regulatory Commission license limitations. These additional radiation-related considerations will, in given instances, greatly complicate the sampling and analysis procedures and will limit the ability to follow typical EPA guidance used for parallel projects conducted in the non-radiological arenas. The development of these DOE guidance documents for the Environmental Restoration Program has been paced so as to address any changes in the QA/QC or documentation guidance as well as any changes in program focuses which may be result from the anticipated update of the QAMS-005/80 or in the possible finalization of the ANSI/ASQC-E4-19xx Standard, "Quality Assurance Program Requirements for Environmental Programs". According to the draft ANSI/ASQC-E4-19xx standard, the development and implementation of DQOs represents a graded-approach based on the intended use of the data and the degree of confidence needed in the quality of the results.⁸ This approach is most developed for the INEL's Environmental Restoration Program since the resultant data is directed to an INEL-wide database to be used in conjunction with current and subsequent phases of the restoration process. The revision process for the QAMS document had been tentatively scheduled for completion in late Spring of 1993 by EPA.

Validators participating in the comprehensive validation of environmental data associated with DOE sites and facilities will have to stay abreast of the status of these parallel programs at DOE and EPA, and must be aware of the status of their interface. For the Environmental Restoration Program's implementation at the various DOE facilities, multiple

Program's implementation at the various DOE facilities, multiple agency/department of government involvements will likely continue, and the validator must know the terms of any inter-agency agreements, consent orders, etc. which are in effect. Specifically, the validator must interface with facility contractor Environmental Restoration project management for an interpretation of data package requirements, required analytical levels, required levels of validation, due dates for deliverables to the regulatory agencies, etc.

At the Idaho National Engineering Laboratory (INEL), Westinghouse Idaho Nuclear Company (WINCO) and other site contractors are jointly participating with DOE-Idaho and its consultants who perform independent technical reviews for DOE-Idaho on specialized technical teams which are addressing program areas such as sample collections, field QC, and the validation of environmental data for the Environmental Restoration Program and other environmental programs. For data validation, statements of work and SOPs have been developed by the site contractors during the current site contract period. During 1992, WINCO and other site contractors began to compare and include aspects of each other's respective programs in order to formulate a consistent approach to the process of data validation and to assist DOE-Idaho in obtaining a smooth transition for the INEL's environmental programs prior to the scheduled 1994 consolidation of the INEL's contract. The anticipated two-fold benefit of these program adjustments is increased cost-effectiveness and maximization of data quality.

BIBLIOGRAPHY

1. "Contract Laboratory Program Statement of Work for Organic Analyses"; U.S. Environmental Protection Agency, 1990.
2. "Data Quality Objectives for Remedial Response Activities - Development Process", EPA/540/G-87/003; U.S. Environmental Protection Agency, 1987.
3. "Estimating the Quality of Environmental Data"; Dale I. Bates, Billy J. Fairless, PhD.; Pollution Engineering, March, 1989.
4. "Guidance for Data Useability in Risk Assessment (Part A)", 9285.7-09A; U.S.EPA, Office of Emergency and Remedial Response, 1992.
5. Code of Federal Regulations, 40CFR Part136.3, 1992.
6. WINCO Standard Operating Procedure N.0.4, 1992.
7. "Guidance for Data Useability in Risk Assessment - Interim", EPA/540/G-90/008; Office of Emergency and Remedial Response, 1990.
8. "Quality Assurance Program Requirements for Environmental Programs", ANSI/ASQC-E4-19xx, Draft, 1991.

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