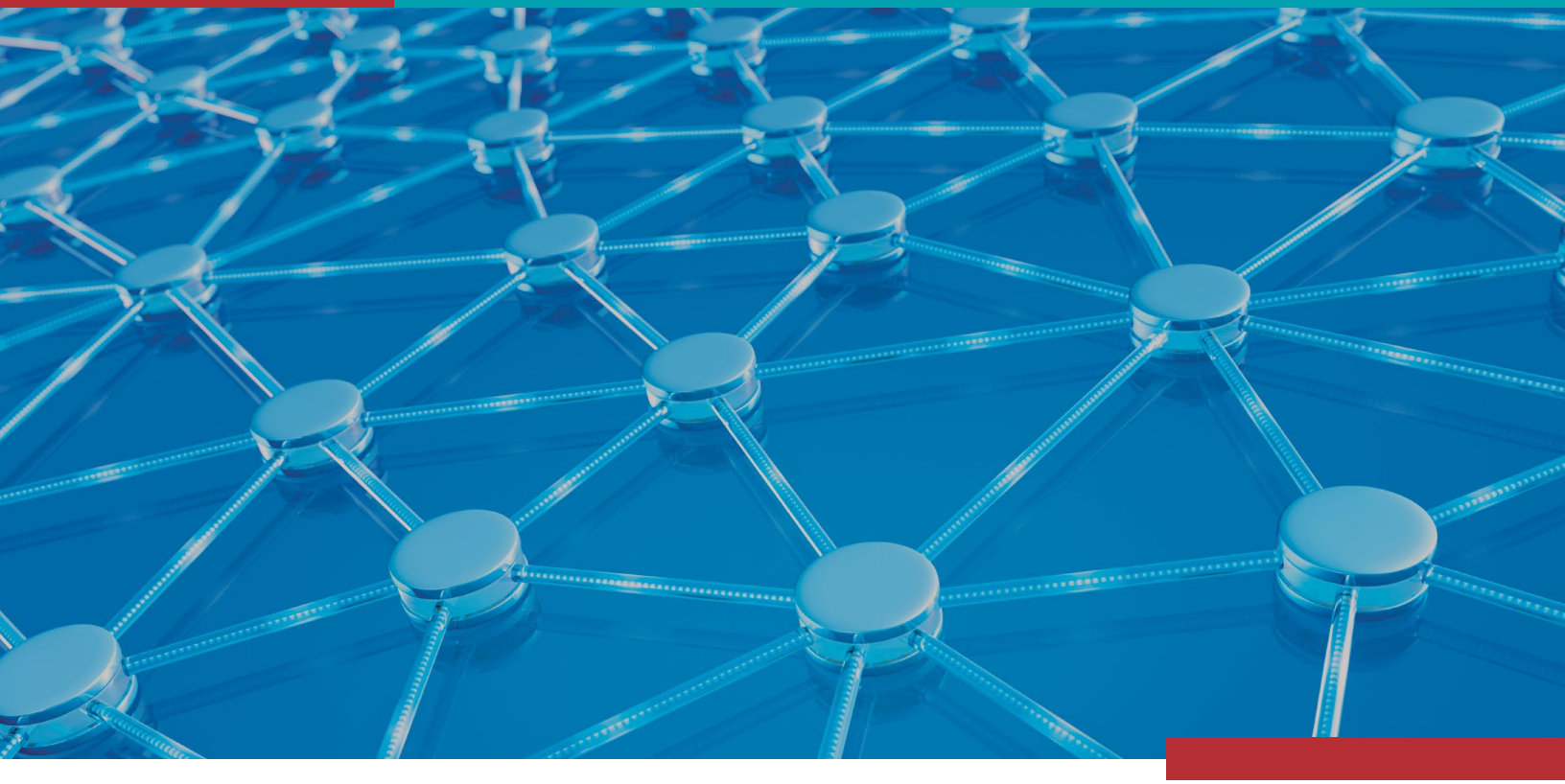
Requirements for Environmental Electronic Data Delivery Submissions

APHL Report



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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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Table of Contents

List of Tables

List of Figures

1. Executive Summary

This document fulfills several next steps identified in a January 2011 white paper, "Environmental Laboratory Electronic Data Management."[1] The audience includes laboratories, information technology (IT) support, laboratory information management systems (LIMS) vendors, data generators, and data consumers, since each have critical roles in electronic data delivery.

APHL proposes a granular-level environmental electronic data deliverable (EDD) with a standardized, defined list of data elements and their associated data structures and components. This EDD is agnostic with regard to method, matrix, or governmental program.

Two EDD data deliverables and their associated data elements are defined. One is transitional, referred to as Type 1t which includes a limited set of data elements and is reported as a spreadsheet. The second includes an expanded set of data elements and is reported as an XML.

This document provides a narrative that describes the:

1. relationship of the collected laboratory data,
2. LIMS,
3. EDD, and
4. data output options.

Additionally, a set of detailed appendices are offered for IT developers that require detailed specifications to construct a data exchange template (DET).

In order to make this a true data standard, next steps include partnering with:

- federal agencies (i.e., EPA, CDC and FDA) on the use of a single, comprehensive data exchange template (DET) and document type definition (DTD), and
- LIMS vendors on a coordinated strategy to implement systems able to automatically support the capture and reporting of a standardized set of data elements as defined in the DET.

[1] APHL . "Environmental Laboratory Electronic Data Management." Available at: http://www.aphl.org/aphlprograms/eh/Documents/EH_2010Dec_EDM_WhitePaper.pdf

2. Background

Environmental health laboratories support many local, state, and federal programs, such as:

- emergency preparedness and response,
- human biomonitoring,
- food safety,
- radiation exposure assessment,
- drinking water quality,
- waste water treatment,
- solid waste testing, and
- environmental exposure assessment.

The data associated with these programs includes chemical, radiological, and microbiology measurements on environmental and clinical samples or specimens. Measurements occur across a wide range of matrices and environmental media as well as use various methods utilized by multiple programs.

In this age of increased electronic communication, it is common for data users to request data from laboratories in a standardized electronic format also known as an electronic data deliverable (EDD). Reporting EDDs saves laboratories time by sending data directly from a laboratory information management system (LIMS), minimizing and possibly eliminating manual data entry.

Additionally, EDDs reduce transcription errors and speed up data delivery. For the data user, EDDs save time by standardizing the data collected from multiple laboratories using multiple analyses. It also allows the use of automated data review software to approve and share data. EDDs minimize the need to harmonize and cleanse data.

Local, state and federal agencies possess different reporting requirements and systems, including unique EDDs with unique data elements and inter-relationships. The existence of multiple EDDs places a large burden on laboratories and reduces the overall ability of public laboratories to network and integrate information.

Even within agencies, there can also be multiple technical implementations of a data standard.[2] Ultimately, support of multiple data deliverables may result in **slower reactions to public health threats, possibly increasing morbidity and mortality.**

The reporting and review of environmental data includes many complexities not typical of clinical data. These complexities contribute to the organic development of multiple data deliverables. For example, environmental data is often numerical (versus positive or negative), method-dependent, and sample-centric. Simple “results” are often not sufficient for reviewers who may wish to view a variety of raw quality control data associated with these results.

[2] For example EPA uses: SCRIBE, eDWR, SDWIS, SEDD, ERLN et al.

In fact, data reviewers increasingly seek to use quality control data to provide accountability for the data set, a concept not addressed with certification. The quality control data is particularly important during multi-agency investigations where laboratories must network together and do not share a common certification requirement. Also, such data is important during emergency response when reviewers may need increased confidence in the data prior to making decisions or posting it for public consumption.

The Association of Public Health Laboratories' (APHL) Environmental Health Committee, Environmental Laboratory Subcommittee, and Informatics Committee are working together to improve environmental LIMS implementation, data exchange, and interoperability.[3] One of their goals was to propose a standard EDD with a defined list of data elements, comprehensive enough to support specific programmatic and data user needs.

APHL envisions laboratories able to provide an EDD that includes the following:

1. analytical method and assurance that the method was followed,
2. raw quality control data associated with the analytical sequence that defines target substance results,
3. unique laboratory analytical measurement or specifications necessary to evaluate the raw data,
4. an audit trail from laboratory data collection to client reporting, and
5. a standard electronic submission format.

By providing this information, data generators and consumers can review a data submission and know that all the data measurements submitted match what the results generated.

LIMS vendors are an important component of successful EDD implementations. LIMS vendors must be able to assure public laboratories that individual LIMS implementations can capture and output the necessary data elements needed to support multiple agency needs. The ability to exchange a defined set of data elements is an important step toward promoting environmental public health laboratory interoperability.

[3] APHL. "Environmental Laboratory Electronic Data Management". Available at: http://www.aphl.org/aphlprograms/eh/Documents/EH_2010Dec_EDM_WhitePaper.pdf.

3. Introduction

In this requirements document, APHL proposes a granular-level environmental electronic data deliverable (EDD) with a standardized, defined list of data elements and their associated data structures and components.[4] Over time, APHL hopes laboratories updating their laboratory information management system (LIMS) will use this EDD to create standardization at the federal, state and local levels. Similarly, as federal, state, and local agencies make changes to reporting requirements, APHL hopes that they will use the detailed specifications contained herein, thus creating data interoperability and increasing efficiency both for data reviewers and generators.

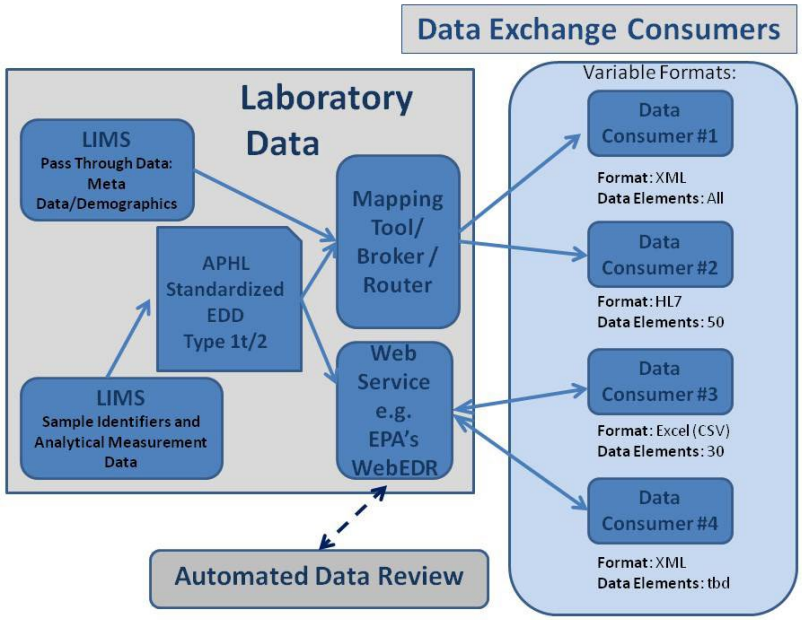
A standardized electronic data deliverable that is method-, matrix- and program-agnostic is consistent with the ability to meet multiple agency reporting needs. The scope of this document does not include the transport nor the vocabulary considerations associated with multiple agencies and programs. Instead, attention focuses on defining the data elements that support the collection of raw data from instruments and the associated data structures. Future work should standardize the terminology associated with these data elements across multiple agencies.

Figure 1 illustrates the relationship of the EDD to a LIMS and multiple electronic data output options. First, the LIMS should collect the raw and quality control data from the analytical instrument. From there, a standardized EDD allows data to be organized using a comprehensive list of data elements and structures. Mapping software facilitates standardized EDD delivery to multiple data consumers, each with unique reporting requirements.

A standardized EDD also facilitates automated data review (ADR) associated with data validation. ADR can replace often-laborious manual review that assures that data are of known quality. Confidence in **data quality is essential for the decision-making process, supporting regulatory enforcement, litigation, and policies regarding human health and safety**.

[4] This APHL requirements document is modeled after EPA's draft "Requirements for Environmental Response Laboratory Network (Type 2) Data Submissions" for environmental public health laboratories to use in LIMS implementations. After reviewing multiple EDDs used to represent environmental data, APHL believes this particular model is the most modern and comprehensive. (www.epa.gov/erln)

Figure 1 Relationship of LIMS, EDD, and Data Output Options



APHL's goal is a universal EDD—one that can be used to support the varied data requirements of multiple agencies such as EPA (including its multiple program offices), CDC, FDA, and others. The proposed EDD is: based on accepted standards, flexible and capable of meeting emerging standards. Components of this goal include:

- The EDD focuses on a set of discrete data elements and their relationship to each other—i.e., how they relate to the collection of analytical measurements (e.g. the analytical sequence). As an example, by collecting the time of a preparation step for each analyte and sample type, the reviewer can compare this time to sample login time and assure that preparation took place in a timely fashion.
- The EDD does not negate the ability of multiple agencies to receive data in their individual, unique reporting formats. Figure 1 (pictured above) illustrates that various reporting formats of electronic data messages can be tailored from the data elements.[5] Standardization allows EDDs with fewer data elements to be easily mapped.
- The use of XML allows the creation of relationships between data elements.
- The EDD focuses on those data elements generated by the laboratory. While associated demographic and metadata is important, this data is very program-specific and does not lend itself to standardization. However, this data can be linked to the laboratory data via reference numbers. For example, many environmental agencies

[5] Many relatively inexpensive third-party tools and data brokers can convert one message type to another, so long as the data elements exist in both messages.

manage metadata through a separate data delivery. This data is often referred to as "pass-through data."

- The EDD comprehensively manages quality control data/measurement quality objectives (MQOs).[6] Collection of quality control data allows results to be validated against measurement quality objectives and promotes accountability.
- A standardized EDD facilitates the use of automated data review (ADR) and validation. Many data consumers may not wish to see quality control data or MQOs, but appreciate knowing that the data was validated. An example is EPA's WebEDR that provides a web service to upload and perform ADR review both within the laboratory and by a reviewer.

APHL believes that laboratories need two reporting formats at this time. The first represents a very simplified option, a spreadsheet labeled the Type 1t (where "t" stands for transition). The preferred XML Type 2 option includes relational data groups, additional measurement quality objectives, and added flexibility.

[6] MQOs are defined as specified performance criteria used in a sampling and analysis plan and may include evaluation of quality control data for completeness, sequence, frequency, correctness, and limits. Fortunately, laboratories typically use a fairly universal approach to collect sample data and associated quality control data. The process for collecting this inclusive set of data is referred to as the "analytical sequence." The more MQOs included in the review of the quality control data in an analytical sequence, the more complete the evaluation. This evaluation assures that the target results are well documented. By linking MQOs to target results for field samples, the data reviewer adds accountability to the data set. While certification and accreditation provide evidence of capability at some point in time, MQOs provide direct accountability to the actual data set. This accountability is particularly useful during surge or when standardized testing is provided with new variables.

2.0 OVERVIEW OF REPORTING REQUIREMENTS

Electronic data deliverable (EDD) formats include:

- an unformatted spreadsheet, where the column header defines the data for that column
- or eXtensible markup language (XML[7]).

The XML format best facilitates the import of data into project-level or enterprise-level relational databases, as well as the processing of the data by automated electronic data review and assessment software. Data is structured and can be nested. It is one of the most popular languages used for communicating data among information systems, and because of this, a plethora of tools exist to assist in reading a file or the generation of a well-formed XML file from an in-house database. Many laboratory information management systems (LIMS) manufacturers provide this functionality as part of their system. Many of the tools available on the market provide a mapping tool that allows a user to point and click to where data is located and map it using a Document Type Definition (DTD), generating a complete XML file based on this mapping. **For these reasons, APHL recommends the XML format over the spreadsheet.**

In order for XML files to remain useful as a common language among systems, certain rules regarding organizing information and syntax used must be followed. XML files must be validated to ensure the file adheres to any business rules established for a program (validation), as well as to XML standards (syntax). Currently, there are two options for determining proper syntax and validation of an XML file: a Document Type Definition (DTD) or an XML Schema Definition (XSD). **Currently, the DTD option is recommended; however, a future goal is to move to XSD.**

Two types of data deliverables are provided in this document. Type 2 is the more robust data standard which utilizes XML formatting. APHL envisions that the Type 2 data deliverable will become the standard. Recognizing that many laboratories are developing electronic capability, a transition is offered that allows a spreadsheet and fewer MQOs. This optional EDD is labeled Type 1 "t" for transition. A Type 1t data deliverable can even be produced manually, an option for laboratories with LIMS implementations still in their infancy. Laboratories may use many off-the-shelf products to create their Type 1t submission.

In addition to format, the two EDD types also differ in content. The Type 1t data submission includes fewer data elements, while the Type 2 data submissions allow the data reviewer to reproduce the analytical sequence to an increased degree and to use the raw data to better evaluate MQOs. Table 1 summarizes the two EDDs.

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[7] XML (an open standard) provides a common way to describe electronic submission in order to transfer data between systems, databases, and organizations. XML files are hierarchical text-based files which consist of elements that describe a piece of data. XML is an accepted standard, it can be read by multiple machines and it has become a standard for business transactions.

Table 1. Summary of Submission Types

Submission Type	Purpose	Scope	Required Electronic Format
Type 1t	Provides a higher-level picture of the result information.	Result information for target and non-target substances of field and lab-generated samples	Spreadsheet
Type 2	Provides information in order to perform an automated assessment on field and laboratory-generated samples.	Type 1t plus substance information for each analysis performed on a field or laboratory-generated sample, including batch information, as well as some calibration information (optional)	XML

2.1 Type 1t Electronic Delivery Requirements

Type 1t data must be reported electronically for every required data element (See Table 1). The following identifies the specific requirements for electronic reporting.

- Report in a computer-readable format: a spreadsheet.
- Ensure that the file contains a column representing the required data with the Type 1t data element names as column names (See Appendix A).
    - A single substance for a sample will constitute a new row within the spreadsheet.
    - Data must be present for all required fields.
    - Several fields will be repeated in each row in order to ensure the project information can be identified for each substance when processing the data. As an example, every unique analyte must be reported in a new row, but the sampleID must be repeated for each row.
- A single spreadsheet should only contain results associated with the designated data reporting group.
- The spreadsheet must be void of any formatting such as text formatting as well as page formatting.

Table 2 provides a short summary of the data elements used in the Type 1t EDD. A complete listing is provided in Appendix A, designed for laboratory/IT personnel responsible for providing environmental electronic data exchange.

Table 2. Type 1t Fact Sheet and Summary of Required Data Elements

Scope	Result information for target and non-target substances of field and lab-generated samples
Electronic Format	Spreadsheet
Hardcopy	Portable Document File (PDF) required; paper upon request
Required Summary Forms	Organize measured results of the reported samples for each of the analytical methods utilized in the analytical testing
Instrument and Other Supporting Data	Not Required

Type 1t Examples of Required Data Elements*:

- SubstanceName
- SampleMatrix
- MethodIdentifier
- SampleIdentifier
- SampleCollectionEndDate
- AnalysisEndDate
- Result
- ResultUnits
- ReportingLimit
- ReportingLimitType
- ReportingLimitUnits
- AnalyticalServiceRequestIdentifier
- OrganizationIdentifier
- ProjectIdentifier
- DataPackageIdentifier
- SubstanceType
- SampleType
- AnalysisStartDate

* Data must be provided for all Elements for each substance provided.

3.0 TYPE 2 DATA SUBMISSION

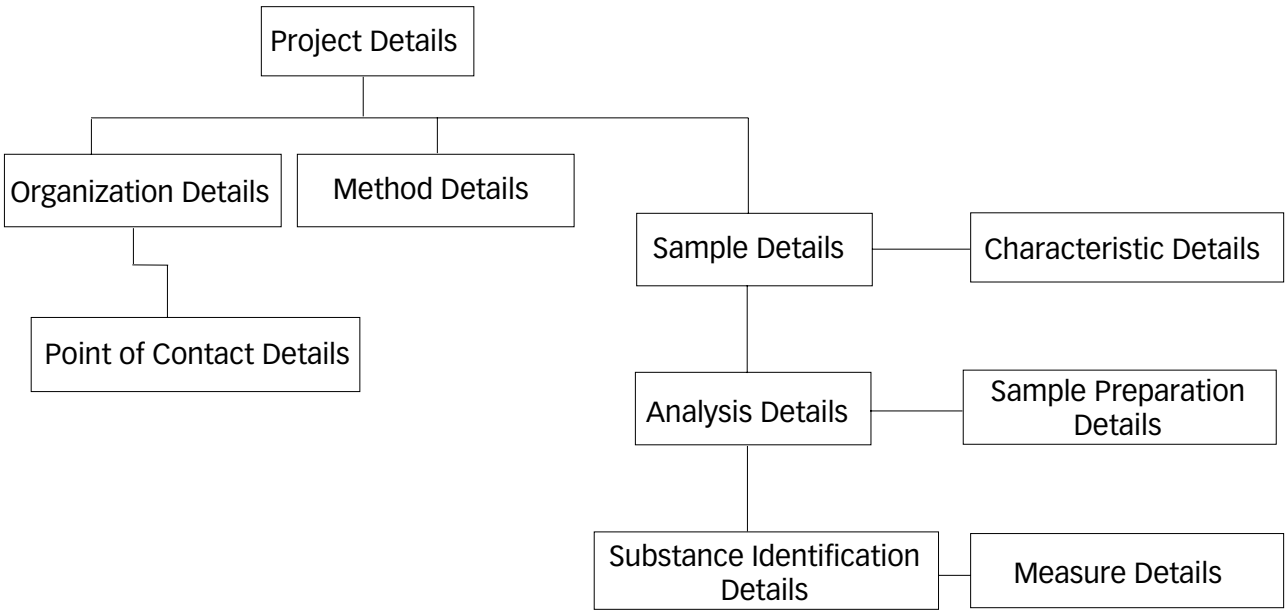
A Type 2 submission provides data users with the ability to perform an automated data assessment based on defined quality objectives. By requiring data to be submitted using eXtensible Markup Language (XML), a Type 2 EDD allows the establishment of the necessary relationships for data validation.

Type 2 focuses on arranging information into groupings that represent key components of the analytical process, allowing both the analytical process to be re-created during data review and for relationships to exist between the different data elements.

Data required from Type 1 is still required in Type 2, but data are now organized under objects that define the relationships between the data. For example, "Sample Identifier" in Type 2 submissions is under the heading (data group) "SampleDetails" because it is descriptive information related to a sample. The use of this format also accommodates the reporting of additional data associated with sample characteristics (e.g., pH, temperature, % moisture, etc.); sample handling; sample preparation; laboratory batching; and sample analysis.

The following diagram depicts the data groups defined by the Type 2 Data Exchange Template (DET), how they relate to one another, and how they are organized for use by a Data Type Definition (DTD). In order for submitted data to pass a validation test, laboratories must organize their XML submissions so that a data group retains the same relationships as the Type 2 DTD.

Figure 2: Type 2 Data Exchange Template and Group Organization



Type 2 formatting presents laboratories with the ability to provide a submission with (or without) calibration data. Type 2 data submissions include:

- laboratory & methods used;
- data associated with sample characteristics, sample handling, preparation, laboratory batching & sample analysis;
- data associated with the substance measured and sample type; and
- measurements associated with the expected result for non-target compounds.

Type 2 also offers the ability for laboratories to report a variety of optional data that a data user can request such as background information regarding the methods used, additional contact information or additional details pertaining to a sample.

Type 2 data elements provide information that allows for automated data review to assess precision, accuracy, sensitivity, selectivity, and representativeness.

3.1 Type 2 Electronic Submission Requirements

Type 2 data shall include all of the elements included in Type 1t; however, additional elements can be included to enable the data user to perform a more extensive data assessment.

Results are reported for each analysis performed on a sample as well as laboratory-generated positive and negative control samples (e.g., laboratory control samples [LCS], duplicates, blanks, etc.). Data are also reported for non-target substances (e.g., surrogates, internal standards, tentatively identified compounds, etc.) along with the results of the sample and laboratory batching information. EPA data users may request that calibration information be provided with a Type 2 submission, which will require the laboratory to provide additional information.

3.2 Data Requirements Summary

The Type 2 Data Exchange Template (DET) defines the specific data elements applicable to each submission type:

- Field-generated samples
- Laboratory-generated (positive & negative control) samples, i.e. LCS, blanks, MS/MSD, etc.
- Target and non-target substances
- Batching information
- Instrument performance & general calibration information
- Tentatively identified compounds

3.3 Electronic Delivery Requirements

Type 2 data must be reported using an XML file meeting DTD requirements:

- Report in a computer-readable format using an XML file.
- Ensure the XML includes the following as the 2nd line in the XML file: <!DOCTYPE ProjectDetails SYSTEM "TYPE 2_GENERAL_1.dtd">.[8]
- Ensure that the XML includes the appropriate syntax.[9]
- Ensure that the XML passes DTD validation; for example, through use of automated data review software such as WebEDR.

[8] See Appendix E: Type 2 Document Type Definition (DTD)

[9] See Appendix C: Data Exchange Template (DET) for Type 2.

4.0 Type Two Fact Sheet

Table 3: Type Two Fact Sheet and Summary of Data Elements

Scope	Type 1t plus substance information for each analysis performed on a field or laboratory-generated sample, as well as any calibration sample (optional)
Electronic Delivery	Extensible Markup Language (XML)
Data Report Delivery	Portable Document File (PDF) required, paper upon request
Required Summary Forms	Type 1t plus additional measurement quality indicator information
Instrument and Other Supporting Data	Not Required

Required Data Elements for Type 2 EDD

- ProjectDetails
- DataPackageIdentifier
- DateFormat
- LaboratoryNarrative
- LaboratoryQualifiers Definition
- ProjectIdentifier
- OrganizationDetails
- OrganizationIdentifier
- MethodDetails
- MethodIdentifier
- SampleDetails
- SampleIdentifier
- SampleChainofCustody Identifier
- SampleCollectionEnd Date
- SampleMatrix
- SampleType
- AnalysisDetails
- AnalysisBatchIdentifier
- AnalysisEndDate
- AnalysisStartDate
- AnalysisType
- InstrumentIdentifier
- LaboratoryAnalysis Identifier
- MethodIdentifier
- SubstanceIdentification Details
- ExclusionIndicator
- ReportingLimit
- ReportingLimitType
- ReportingLimitUnits
- Result
- ResultUnits
- SubstanceName
- SubstanceType
- RunBatchIdentifier

The following comprehensive appendixes are provided for laboratory or information technology personnel responsible for providing environmental electronic data exchange. The reader is also advised of the downloadable file “ERLN_General_1.dtd” that is used for Type 2 data exchange.

APPENDIXES:

- Appendix A provides a detailed Data Exchange Template for Type 1t format.
- Appendix B provides a comparison of the differences in Type 1t and Type 2 required data elements.
- Appendix C provides a detailed Data Exchange Template for the Type 2 format.
- Appendix D provides a detailed XML reporting guide.
- Appendix E provides the Type 2 Document Type Definition. For convenience this DTD is also available online.

Appendix A: Type 1t Data Submission

Type 1t EDDs provide the ability to report the most basic results information for target substances of field samples. In order to ensure that more laboratories can provide data electronically, Type 1t submissions do not require eXtensible Markup Language (XML); rather, the data is provided as a spreadsheet. The data formatting remains simple, but Type 1t transitions to Type 2 by adding data on laboratory-generated quality control substances such as blanks, laboratory control samples, and spikes, etc.

Type 1t provides the foundation for Type 2 data submissions by including result information for laboratory-generated samples and non-target compounds. By providing this information, data users are able to view a broader picture of the data being submitted. Type 1t data shall include final result information for target and non-target substances of field-generated and laboratory-generated samples. Results from laboratory-generated positive and negative control samples (e.g., LCS, blanks, etc.) should also be reported.

Type 1t data submissions shall include the information detailed in the following table for every target substance of a field-generated sample.

Definitions for the Table

Required Data Elements: Define the basis for information necessary to identify the project, electronic submission, and minimum information necessary for the data submission type. Required data elements must contain a value and be reported at all times. Required is indicated in the table below by an "R."

Conditionally-required Data Elements: Defines additional elements that are required should a certain condition exist in the data submission. Conditional elements are only required if the analytical methodology requires the use of the elements indicated as conditional. Conditionally required is indicated by a "C."

Optional Data Elements: Defines information that a data user may want to request, or a laboratory may want to provide, in addition to the required or conditionally-required elements for a submission type. Data elements identified as optional do not need to be reported unless requested by the data user. Optional is indicated by an "O."

Note: Valid Values for several of the data elements share values used with the EPA Staged Electronic Data Deliverable (SEDD) http://www.epa.gov/fem/pdfs/sedd52_valid_values.pdf

Additional instructions for the submission of Type 1t:

- Format for the content of all data elements is string/text.
- All date fields must be reported according to EPA's ISO-based Representation of Date and Time Data Standard, Standard No.: EX000013.1 (e.g., YYYY-MM-DD hh:mm:ss).
- All times MUST be based on a 24-hour clock. Time zones are not included in this data element.
- Data tags with an asterisk (*) will contain repetitive content. The information for these data tags should be repeated in every row.
- A single substance for a sample will constitute a new row within the spreadsheet.
- The spreadsheet must be void of any formatting that can be applied using off-the-shelf products such as text formatting (bold, italics, underline), column formatting (date, general, number, custom), page formatting, hidden columns or rows, additional column names, calculated field values, or referenced fields.
- The order of the columns is not important; however, the column headings must be exactly as listed in the Tag in Table 4.

Table 4: Type 1t Data Requirements

Data Exchange Template (DET) Tag	Definition	Business Rules/Comments	Usage	Format
AgreementNumber*	A client-defined number or identifier that specifies the contract or agreement under which the laboratory analyzes the samples.	Provide if a contract number exists, if not, leave blank.	C	Alphanumeric
AnalysisStartDate	The date (and time, if required) of analysis of a sample aliquot or standard. If analyzed over a range of dates, this is the start date.		R	YYYY-MM-DD hh:mm:ss
AnalysisEndDate	The date (and time, if required) of the end of the analysis period, if the sample aliquot or standard was analyzed over a period of time.	The date should reflect the end of the analysis performed by an instrument; it does not relate to the time in which an analyst completed their review of an analysis.	R	YYYY-MM-DD hh:mm:ss
AnalyticalService RequestIdentifier*	A client-defined number or identifier that specifies the service request.	Obtain from Analytical Service Requester (ASR).	R	Alphanumeric
CASRegistryNumber	The unique number assigned by Chemical Abstracts Service (CAS) to a chemical substance.	Provide when the substance has a defined CAS number, if not, leave blank.	C	Alphanumeric
Comment	A free-form comment field. Information relating to the data on a particular “row”- e.g. comments relating to the SampleType or SubstanceType or Result etc		O	Alphanumeric
DataPackageIdentifier*	A laboratory-defined identifier for this data submission package. This identifier applies to a single EDD.		R	Alphanumeric
ExpectedResult	The expected final result of a substance that has been spiked into an aliquot at any time during the analysis process, or the true value of a substance in the sample analyzed.	Provide if spiked substance was added to a sample for analysis. The expected result is what should be found in the substance. If the substance was not spiked, leave blank.	C	Alphanumeric
ExpectedResultUnits	Units associated with expected result.	Provide if reporting expected result, if not, leave blank.	C	Alphanumeric

Data Exchange Template (DET) Tag	Definition	Business Rules/Comments	Usage	Format
LaboratoryResult Qualifier	A laboratory-assigned string of result qualifiers (usually a single character for each qualifier), based on client-defined rules and values. Similar to "interpretation" used in clinical submissions	In order to stay consistent from one submission to another, the only qualifiers that will be used are "U", "J", and "UJ".[10]	R	Alphanumeric
LaboratorySample Identifier	A laboratory-defined identifier for a sample that uniquely identifies a single sample that is subjected to an analysis.		O	Alphanumeric
LaboratorySubstance Identifier	A laboratory-defined identifier for a substance.		O	Alphanumeric
LocationIdentifier	A client-defined identifier of the sampling location at a particular site.		O	Alphanumeric
Method/Identifier	The identification number assigned by the method publisher.	Obtain from ASR.	R	Alphanumeric
OrganizationIdentifier*	A designator used to uniquely identify a unique business establishment within a context.	Obtain from ASR. If one is not provided, the laboratory shall include an identifier for their name.	R	Alphanumeric
OrganizationName*	Descriptive name for the laboratory performing this analysis.		O	Alphanumeric
PreparationEndDate	Date and time of sample preparation. Preparation is used generally to include method specific techniques such as extraction, digestion, and separation. If prepared over a range of dates, this is the start date.	Provide end date and time in YYYY-MM-DD hh:mm:ss format if a preparation was performed on the sample. If a preparation was performed the start and end date must be provided, if not, leave blank.	C	YYYY-MM-DD hh:mm:ss
PreparationStartDate	The date and time of the preparation of this sample aliquot. Preparation is used generally to include method specific techniques such as extraction, digestion, and separation. If prepared over a range of dates, this is the start date.	Provide start date and time in YYYY-MM-DD hh:mm:ss format if a preparation was performed on the sample. If a preparation was performed the start and end date must be provided, if not, leave blank.	C	YYYY-MM-DD hh:mm:ss

[10] "U" indicates that the substance was analyzed for, but not detected. "J" indicates an estimated value. The "J" qualifier is used when a QC parameter indicates that the reported quantity could be inaccurate, or when the data indicates the presence of a substance that meets the identification criteria, but the result is less than the sample quantitation limit, but greater than zero. The "UJ" qualifier indicates that the substance was analyzed for, but not detected, and a QC parameter indicated that the reporting limit could be inaccurate.

Data Exchange Template (DET) Tag	Definition	Business Rules/Comments	Usage	Format
ProjectIdentifier*	A designator used to uniquely identify the project to organizations sharing data.		R	Alphanumeric
ReportingLimit	The number or value below which data is typically reported as 'not detected' for the substance being measured.		R	Alphanumeric
ReportingLimitType	One of a list of client, regulation, or organization-defined acronyms or statistical methodologies that specify the type of reporting limit.		R	Alphanumeric
Reporting LimitUnits	Units associated with reporting limit as determined by the laboratory.		R	Alphanumeric
Result	The reportable measure of the result for the chemical, microbiological, or other characteristic being analyzed.		R	Alphanumeric
Result Basis	The basis upon which the final results were calculated.	Provide the result basis if the result has been modified to account for a sample characteristic such as % moisture, % solids. Use the SEDD Valid Values for "ResultBasis" to determine an appropriate value for this element."	C	Alphanumeric
ResultUncertainty	A value or set of values that characterizes the dispersion of the values that could reasonably be attributed to the measured result value.	For Radiochemical Analysis only at this time. Ensure that Uncertainty is expressed in same Result Unit as the Result. If there is no uncertainty, leave blank.	C	Numeric
ResultUnits	The code that represents the unit for measuring the item.		R	Alphanumeric
SampleCollectionStart Date	Date and time the sample was collected. If collected over a range of dates, this is the start date.	For laboratory-generated QC samples not associated with a field sample, enter the end date/time QC samples were prepared by the laboratory.	O	YYYY-MM-DD hh:mm:ss
SampleCollectionEnd Date	The ending date that a field activity was finished.	Enter start date for grab samples.	R	YYYY-MM-DD hh:mm:ss

Data Exchange Template (DET) Tag	Definition	Business Rules/Comments	Usage	Format
SampleIdentifier	A designator used to uniquely identify a sample within a context.	Obtain from Chain of Custody. If reporting a laboratory-generated sample, provide the laboratory sample identifier as the SampleIdentifier.	R	Alphanumeric
SampleMatrix	Sub-medium or matrix that is sampled.	Obtain from Chain of Custody. If reporting a laboratory-generated sample, provide the matrix of the appropriate field sample.	R	Alphanumeric
SampleType	The client-defined term used to define the specific type of sample being analyzed. Examples include: Field_Sample and QC samples such as: MatrixSpike, Matrix_ Spike_Duplicate Laboratory_Control_ Sample.	Use the SEDD Valid Values list for "QCType" to determine an appropriate value for this element.	R	Alphanumeric
SubstanceName	The name assigned to a chemical, biological, or radiological substance or feature that describes it in terms of its molecular composition, taxonomic nomenclature, or other characteristic.	Use the SEDD Valid Values instructions for "Analyte name" and "AnalyteNameContext" to determine an appropriate value for this element. Refer to the appropriate official publication for a list of analyte name valid values. Approved analyte name lists are provided by: • The Chemical Abstracts Service (CAS) nomenclature, based on the 9th Collective Index rules • The International Union of Pure and Applied Chemistry • The Environmental Protection Agency's (EPA's) Substance Registry System (www.epa.gov/srs/).	R	Alphanumeric
SubstanceType	A client-defined identifier that identifies the type of substance reported, e.g. Target,Surrogate.	Use the SEDD Valid Values list for "AnalyteType" to determine an appropriate value for this element.	R	Alphanumeric

* Repeat data for each row included in the electronic submission.

Appendix B: Comparison of Type 1t and Type 2 Required Data Elements

Definitions for the Table

Required Data Elements: Define the basis for information necessary to identify the project, electronic submission, and minimum information necessary for the data submission type. Required data elements must contain a value and be reported in the data submission at all times. Required is indicated by an "R" in the DET. Data cannot be considered acceptable if required data is missing.

Conditionally-required Data Elements: Defines additional elements that are required should a certain condition exist in the data submission. Conditional elements are only required if the analytical methodology used requires the use of the elements indicated as conditional. Conditionally-required is indicated by a "C" in the DET.

Optional Data Elements: Defines information that a data user may want to request, or a laboratory may want to provide, in addition to the required or conditionally-required elements for a submission type. Data elements identified as optional do not need to be reported, unless requested by the data user. Optional is indicated by an "O" in the Type 2 DET.

Not Required Data Elements: Defines information that an EPA data user will not use and are not necessary for automated processing. This listing illustrates the simplicity of the Type 1t data submission compared to the Type 2. Data elements identified as not required cannot be electronically reported. Not required is indicated by a "-" in the DET.

TYPE 2 Data Group	TYPE 2 Data Element	Usage in Type 1t	Usage in Type 2
ProjectDetails	AgreementModificationDescription	-	O
ProjectDetails	AgreementModificationIdentifier	-	O
ProjectDetails	AgreementNumber	O	O
ProjectDetails	AnalyticalServiceRequestIdentifier	R	R
ProjectDetails	Comment	O	O
ProjectDetails	DataPackageIdentifier	R	R
ProjectDetails	DataPackageName	-	O
ProjectDetails	DataPackageVersion	-	O
ProjectDetails	DateFormat	-	R
ProjectDetails	LaboratoryNarrative	-	R
ProjectDetails	LaboratoryQualifiersDefinition	-	R
ProjectDetails	LaboratoryReportedDate	-	O
ProjectDetails	ProjectIdentifier	R	R

TYPE 2 Data Group	TYPE 2 Data Element	Usage in Type 1t	Usage in Type 2
ProjectDetails	ProjectName	-	O
OrganizationDetails	Comment	-	O
OrganizationDetails	OrganizationIdentifier	R	R
OrganizationDetails	OrganizationLocationAddress	-	O
OrganizationDetails	OrganizationLocationAddressCity	-	O
OrganizationDetails	OrganizationLocationAddressCountry	-	O
OrganizationDetails	OrganizationLocationAddressState	-	O
OrganizationDetails	OrganizationLocationAddressZipCode	-	O
OrganizationDetails	OrganizationMailingAddress	-	O
OrganizationDetails	OrganizationName	O	O
OrganizationDetails	OrganizationTelephoneNumber	-	O
OrganizationDetails	OrganizationType	-	O
PointofContactDetails	Comment	-	O
PointofContactDetails	ContactElectronicAddress	-	O
PointofContactDetails	ContactFullName	-	O
PointofContactDetails	ContactIdentifier	-	O
PointofContactDetails	ContactTitle	-	O
PointofContactDetails	ContactType	-	O
SampleDetails	ContactIdentifier	-	O
SampleDetails	LaboratoryReceiptDate	-	O
SampleDetails	LaboratorySampleIdentifier	O	O
SampleDetails	LocationIdentifier	O	O
SampleDetails	Preservative	-	C
SampleDetails	SampleChainofCustodyIdentifier	-	R
SampleDetails	SampleCollectionEndDate	R	R
SampleDetails	SampleCollectionStartDate	O	O
SampleDetails	SampleIdentifier	R	R
SampleDetails	SampleMatrix	R	R
SampleDetails	SampleType	R	R
SampleDetails	StorageBatchIdentifier	-	C
AnalysisDetails	AnalysisBatchIdentifier	-	R

TYPE 2 Data Group	TYPE 2 Data Element	Usage in Type 1t	Usage in Type 2
AnalysisDetails	AnalysisEndDate	R	R
AnalysisDetails	AnalysisStartDate	R	R
AnalysisDetails	AnalysisType	-	R
AnalysisDetails	Comment	O	O
AnalysisDetails	ContactIdentifier	-	O
AnalysisDetails	InstrumentIdentifier	-	R
AnalysisDetails	LaboratoryAnalysisIdentifier	-	R
AnalysisDetails	LaboratoryFileIdentifier	-	O
AnalysisDetails	MethodIdentifier	R	R
AnalysisDetails	PreparationBatchIdentifier	-	C
AnalysisDetails	ResultBasis	O	O
AnalysisDetails	RunBatchIdentifier	-	R
SamplePreparationDetails	CleanupBatchIdentifier	-	C
SamplePreparationDetails	CleanupType	-	C
SamplePreparationDetails	ContactIdentifier	-	O
SamplePreparationDetails	MethodIdentifier	-	O
SamplePreparationDetails	PreparationEndDate	C	C
SamplePreparationDetails	PreparationStartDate	C	C
SamplePreparationDetails	SampleDataGroupType	-	C
SubstanceIdentificationDetails	CASRegistryNumber	C	C
SubstanceIdentificationDetails	ExclusionIndicator	-	R
SubstanceIdentificationDetails	ExpectedResult	C	C
SubstanceIdentificationDetails	ExpectedResultUnits	C	C
SubstanceIdentificationDetails	LaboratoryResultQualifier	C	C
SubstanceIdentificationDetails	LaboratorySubstanceIdentifier	O	O
SubstanceIdentificationDetails	ReportingLimit	R	R
SubstanceIdentificationDetails	ReportingLimitType	R	R
SubstanceIdentificationDetails	ReportingLimitUnits	R	R
SubstanceIdentificationDetails	Result	R	R
SubstanceIdentificationDetails	ResultBasis	O	O
SubstanceIdentificationDetails	ResultUncertainty	O	O

TYPE 2 Data Group	TYPE 2 Data Element	Usage in Type 1t	Usage in Type 2
SubstanceIdentificationDetails	ResultUnits	R	R
SubstanceIdentificationDetails	SubstanceName	R	R
SubstanceIdentificationDetails	SubstanceType	R	R
CharacteristicDetails	CharacteristicName	-	C
CharacteristicDetails	CharacteristicType	-	C
CharacteristicDetails	CharacteristicUnits	-	C
CharacteristicDetails	CharacteristicValue	-	C
CharacteristicDetails	Comment	-	O
MethodDetails	Comment	-	O
MethodDetails	MethodCategory	-	O
MethodDetails	MethodCodeType	-	O
MethodDetails	MethodDescription	-	O
MethodDetails	MethodIdentifier	-	R
MethodDetails	MethodLevel	-	O
MethodDetails	MethodModificationDescription	-	O
MethodDetails	MethodModificationIdentifier	-	O
MethodDetails	MethodName	-	O
MethodDetails	MethodSourceName	-	O
MethodDetails	MethodType	-	O
MethodDetails	MethodVersion	-	O
MeasureDetails	MeasureName	-	C
MeasureDetails	MeasureQualifierCode	-	C
MeasureDetails	MeasureUnitCode	-	C
MeasureDetails	MeasureValue	-	C
	Total Required:	18	29
	Total Conditionally Required:	6	22
	Total Optional:	9	48

Appendix C: Data Exchange Template (DET) for Type 2

A Data Exchange Template (DET) comprises a standardized format that identifies the types of information required or allowed in a particular document or data exchange. Data exchange templates contain no data, but rather define the format for exchange (according to data standards and trading partner agreements). Type 1t data has no relational concepts and so it has no DET.

Information included in this DET represents several different types of data necessary to eventually recreate the analytical process of the laboratory. This includes information to indicate:

- what laboratory and instrument quality control samples are associated with field-generated samples (Batching),
- what analyses were used to come to a final result (Analysis grouping), and
- those substances that are the combination of other substances (Substance grouping).

This information ensures that data is put in the appropriate context and provides data users with a complete understanding of how the information was derived.

Data Groups

The Type 2 DET categorizes like data together, identifying similarities, and then summarizing this information so that one data element could be used to represent multiple options. This solves a significant problem associated with using Document Type Definitions (DTDs) as a validation method: DTDs are limiting when additions or modifications need to be made to the data elements required by a reviewer. For example, if a new data element needs to be added, an update to the DTD would be necessary and laboratories would then need to change their methods for generating an eXtensible Markup Language (XML) document. By providing a generic "data group" for these similar data elements ("MeasureDetails"), values can be added without impacting the DTD or a laboratory's setup for generation of XML files.

The Type 2 DET contains several categories of data that require frequent modifications over time. For example, there is a seemingly endless list of what can be considered measures (which comprise a major component of any data associated with an analytical process) but there is a limited list of what a data user would need to know about a measure. In other published exchange models, measurements are individual data elements in the model.

In the Type 2 DET, measures are reported as a data group and an individual measure is reported as a value in the group. An example of this is 'Amount Added' which would be the value for the MeasureName data element (instead of the data element itself) and units would be a value of the MeasureUnitCode data element in the MeasureDetails data group. This concept allows for the expansion of the data standard without disrupting the existing process for providing and validating data.

This concept applies to several groups in the DET, including the MeasureDetails and CharacteristicDetails data groups. The groups should be repeated under their appropriate primary group whenever a different measure or characteristic is called for.

Relational Groups

Another concept applied to the DET is a relational approach to reporting data using DTDs. Typically, data can only be reported as a hierarchy when validating against a DTD, which is why the future Type 2 hopes to use XML schemas for validation. In order to introduce this concept with the current Type 2 standard, the OrganizationDetails, PointOfContactDetails, and MethodDetails group are implemented as relational groups[11].

To eliminate the need to report data in multiple places, the Type 2 relational group does not need to be included as a sub-group under a primary group. Instead, a data element exists within a data group that provides information in order for automated systems to establish a relationship between the data group that the element is reported in and a related data group. A 'relational' relationship provides the ability to reference another data group by providing some form of an identifier.

Specific Type 2 Data Groups

A "data group" defines what type of information is being reported in the group. The following are the Type 2 DET data groups along with their associated descriptions.

Table 5. Data Group Definitions

Data Group Name	Definition
ProjectDetails	Describes the format and content unique to a specific electronic data submission as it relates to a specific project.
OrganizationDetails	Describes the unique framework of authority within which a person or persons act, or are designated to act, towards some purpose.
PointOfContactDetails	Describes the particular terms regularly connected with a person so that you can recognize, refer to, or address him or her.
SampleDetails	Describes one sample analyzed under the criteria established for the project.
SampleHandlingDetails	Describes any manipulation of the sample (e.g., leaching, filtering, and ashing) prior to taking a sample aliquot for analysis.
AnalysisDetails	Describes one complete sequence of events, from taking a sample aliquot through the measurement process, as defined as part of one method.
SamplePreparationDetails	Describes a preparation or cleanup process as part of an analysis.
SubstanceIdentificationDetails	Describes the substance level data from one analysis or one group of analyses.
InstrumentResponseDetails	Identifies and reports the actual measurement data related to the analysis of substance peaks.
InstrumentResponseAdditional Details	A group of data elements that identifies cross-peak comparisons, multiple exposure readings, or data related to the comparison of two or more substances, such as those data elements that describe the effects of potentially-interfering substances on a peak.

[11] DTD, or Document Type Definition, and XML Schema, which is also known as XSD, are two ways of describing the structure and content of an XML document. In summary, schemas are a richer and more powerful of describing information than what is possible with DTDs.

Data Group Name	Definition
CharacteristicDetails	Identifies and quantifies the intrinsic characteristics associated with a sample as received by a laboratory, or after the sample has been processed through a handling or preparation method.
MethodDetails	Describes the procedures and techniques required to determine the methods used to obtain a result.
MeasureDetails	Identifies the value and the associated units of measure for measuring an observation or analytical result value.
DataQualityIndicatorDetails	Describes the quantitative and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user.

Data Element Value Formats

There are five types of data that can be used for a data element:

- **Boolean:** Allows only one of two values; true and false (Y or N).
- **Date:** The date format established is YYYY-MM-DD hh:mm:ss which is based on ISO 8601:2004. The technical representation of this date is YYYY-MM-DDThh:mm:ss where 'T' represents a space.
- **Limited List:** Defines a restricted list of values for a particular data element. Valid values are typically provided by the requester.
- **Numeric:** Allows for integer, decimal, or exponential formats for reporting numeric data.
- **Text:** Allows any value and format to be entered for a data element; this includes numeric values.

The "MeasureDetails" Data Group and the "CharacteristicsDetails" Data Group

One problem with traditional fixed data element DETs is that there is little allowance for a new data element to be used without publishing a new DET. There are many examples of data elements that may be useful for a particular project on a one-time basis.

Laboratories need a way to allow optional or occasionally-needed data elements to be available without having to publish a new DET. One way to "solve" this concern is to provide a "MeasureDetails" data group and a "CharacteristicsDetails" data group. These data groups allow new measurements to be collected and reported "on-the-fly". Table 6 provides some examples of analytical measurement data elements that might be useful in a particular project. Also provided is a list of some examples of sample characteristics that might be useful to describe a sample. These lists of optional data elements can be very large, and many may never be used by a laboratory.

This flexibility of these two data groups allows new measurement values to be collected without the need to create a new DTD. The following list is a list of examples of optional measure names that a laboratory may provide and suggestions regarding data groups for which the

measurements may be used. Each of the measures listed here can have additional attributes such as units and value which should be reported using the data elements available in the MeasureDetails data group. For example AmountAdded would be reported by populating the MeasureName data element with “Added Amount” and the MeasureValue data element with the actual value. There is no limit to the number of measure names that can be used. The MeasureName data elements can have any name that the service requestor and service provider agree upon.

Table 6. Examples of Possible Measurements that the MeasureDetails Data Group Can Handle

MeasureName	Applicable Data Groups
AddedAmount	SubstanceIdentificationDetails
AliquotAmount	AnalysisDetails, SamplePreparationDetails
AnalysisDuration	AnalysisDetails, SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
AnalyzedAmount	AnalysisDetails
BiasErrorRatio	SubstanceIdentificationDetails, InstrumentResponseDetails
CalibrationFactor	SubstanceIdentificationDetails, InstrumentResponseDetails
CorrectionFactor	AnalysisDetails, SamplePreparationDetails
CorrelationCoefficient	SubstanceIdentificationDetails, InstrumentResponseDetails
CountingError	SubstanceIdentificationDetails, InstrumentResponseDetails
Counts	AnalysisDetails, InstrumentResponseDetails
DilutionFactor	AnalysisDetails
Drift	AnalysisDetails, InstrumentResponseDetails
Efficiency	SamplePreparationDetails, AnalysisDetails, SubstanceIdentificationDetails, InstrumentResponseDetails
Energy	InstrumentResponseDetails, InstrumentResponseAdditionalDetails
FilterSize	SampleDetails, SampleHandlingDetails, SamplePreparationDetails, AnalysisDetails
FinalAmount	SamplePreparationDetails, AnalysisDetails
FlowRate	AnalysisDetails
Frequency	InstrumentResponseDetails, InstrumentResponseAdditionalDetails
Gradient	AnalysisDetails
HandlingDuration	SampleHandlingDetails
InitialAmount	SampleHandlingDetails, SamplePreparationDetails
InjectionVolume	AnalysisDetails

MeasureName	Applicable Data Groups
MeanRelativeResponseFactor	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
MeanRetentionTime	SubstanceIdentificationDetails, InstrumentResponseDetails
NumberOfDilutions	AnalysisDetails
PeakRatio	InstrumentResponseDetails, InstrumentResponseAdditionalDetails
PercentDifference	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
PercentRecovery	SubstanceIdentificationDetails, InstrumentResponseDetails
PercentRelativeStandardDeviation	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
Quench	AnalysisDetails
RelativeResponse	SubstanceIdentificationDetails
RelativeResponseFactor	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
RelativeRetentionTime	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
RelativePercentDifference	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
RelativeRetentionTime	InstrumentResponseDetails
Resolution	AnalysisDetails, SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
Response	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
RetentionTime	SubstanceIdentificationDetails, InstrumentResponseDetails
SampleAmount	SampleDetails, SampleHandlingDetails, SamplePreparationDetails, AnalysisDetails
ScreenResult	SampleDetails
SignalToNoiseRatio	SubstanceIdentificationDetails, InstrumentResponseDetails
StandardConcentration	SubstanceIdentificationDetails
StandardFinalAmount	SubstanceIdentificationDetails
StandardDeviation	SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
Wavelength	AnalysisDetails, SubstanceIdentificationDetails, InstrumentResponseDetails, InstrumentResponseAdditionalDetails
Yield	AnalysisDetails

Example Characteristics

The Type 2 DET allows laboratories to report any number of characteristics by using the CharacteristicDetails data group. The following is a list of examples of optional characteristics that a laboratory should provide.

- Artifacts
- Boiling Point
- Clarity
- Color
- Column Diameter
- Column Length
- Conductance
- Density
- Melting Point
- Odor
- Percent Lipids
- Percent Moisture
- Percent Phase
- Percent Solids
- pH
- Refractive Index
- Temperature
- Texture
- Turbidity

DET Data Element Definitions

The following list provides definitions, the intended reporting format, and categorization for each data element within the Type 2 DET.

Table 7. TYPE 2 DET Data Element Definitions

Data Element	Format	Category	Business Rule	Definition
Agreement Modification Description	Text	Description		Text that describes any modifications made to the laboratory's contract.
Agreement Modification Identifier	Text	Description		A client-defined identifier for any modifications made to the laboratory's contract.
AgreementNumber	Text	Identification		A client-defined contract number that specifies the contract or agreement under which the laboratory analyzes the samples.
AnalysisBatch Identifier	Text	Association/ Grouping		A laboratory-defined identifier that is used to link multiple analyses done on one instrument, associated with one or more instrument quality control samples, at which the instrument is checked to be in control at the beginning of an analysis sequence.
AnalysisEndDate	Date	Date		The date (and time, if required) of the end of the analysis period, if the sample aliquot or standard was analyzed over a period of time.
AnalysisStartDate	Date	Date		The date (and time, if required) of analysis of a sample aliquot or standard. If analyzed over a range of dates, this is the start date.
AnalysisType	Limited List	Categorization		A term used to define the type of analysis (e.g., initial, confirmation, MSA). This term is also used to uniquely identify a single analysis from multiple analyses that are used to generate a single result.
AnalyticalService RequestIdentifier	Text	Identification		A client-defined number or identifier that speicifies the service request.
CASRegistry Number	Text	Identification		The Chemical Abstract Service (CAS) registry number for a substance.
CharacteristicName	Text	Description		A descriptive term used to identify the characteristic being measured.

Data Element	Format	Category	Business Rule	Definition
CharacteristicType	Text	Categorization		A term that identifies the type of characteristic being reported.
CharacteristicUnits	Limited List	Categorization		Units for the value of a characteristic.
CharacteristicValue	Numeric or Text			A measured or observed value for the characteristic being reported. The value can either be numeric or text based on the characteristic being reported.
CleanupBatch Identifier	Text	Association/ Grouping		A laboratory-defined identifier that is used to link multiple sample aliquots that are cleaned up together for processing by one method.
CleanupType	Limited List	Categorization		A term that identifies the specific cleanup performed when multiple options are given within the referenced method.
Comment	Text	Comment		A free-form remark, observation, explanation, or expansion text that can occur in any parent data element.
ContactElectronic Address	Text	Description		The electronic address (e-mail) of the person at the laboratory who takes final responsibility for the data.
ContactFullName	Text	Description		The person at the laboratory who takes final responsibility for the data.
ContactIdentifier	Text	Identification	Identifier shall be used as the relational key for data groups to reference a particular contact.	A laboratory-defined unique identifier for an individual within an organization.
ContactTitle	Text	Description		The job title of the person at the laboratory who takes final responsibility for the data.
ContactType	Limited List	Categorization		The type of the person at the laboratory who takes final responsibility for the data.
DataPackage Identifier	Text	Identification		A laboratory-defined identifier for this data deliverable package. This identifier applies to a single deliverable.
DataPackage Name	Text	Description		A laboratory-defined title for this data deliverable package.

Data Element	Format	Category	Business Rule	Definition
DataPackageVersion	Text	Description		If the laboratory resubmits a data package, this data element distinguishes between the different versions.
DateFormat	Text	Description		A value that specifies the format of all reported date/time values in an electronic data deliverable. This value can incorporate the time zone, if required.
ExclusionIndicator	Boolean	Indicator/Boolean	Only report a value when not included.	Indicates whether or not this item is to be excluded or evaluated as part of this data package.
ExpectedResult	Text	Result Measurement		The expected or theoretical result of a substance that has been spiked into a sample aliquot or a standard at any time during the analysis process.
ExpectedResult Units	Limited List	Result Measurement		Units for the expected result.
InstrumentIdentifier	Text	Identification		A laboratory-defined identifier for an instrument.
LaboratoryAnalysis Identifier	Text	Identification		A laboratory-defined identifier for an analysis that uniquely identifies a single run for a single sample aliquot or standard. This identifier must be unique for at least all of the analyses reported in a single deliverable, in the context of one method.
LaboratoryFile Identifier	Text	Identification		The file, and path if required, name where the raw data from the analysis is stored in the laboratory.
LaboratoryNarrative	Text	Description		A laboratory textual account that describes any appropriate information about anomalies that may have occurred during the analysis or review of the data in the electronic data deliverable.
Laboratory QualifiersDefinition	Text	Description		A formal statement of the meaning or significance of any lab qualifier(s) reported by the laboratory.
LaboratoryReceipt Date	Date	Date		The date (and time, if required) that the sample was received in the laboratory.
Laboratory ReportedDate	Date	Date		The date (and time, if required) that the data package was reported by the laboratory to the client.

Data Element	Format	Category	Business Rule	Definition
LaboratoryResult Qualifier	Text	Description		A laboratory-assigned string of result qualifiers (usually a single character for each qualifier), based on client -defined rules and values.
LaboratorySample Identifier	Text	Identification		A laboratory-defined identifier that uniquely identifies a single sample that is subjected to an analysis. The Laboratory Identifier should only be reported in addition to the Sample Identifier.
Laboratory SubstanceIdentifier	Text	Identification		A laboratory-defined identifier for a substance.
LocationIdentifier	Text	Identification		A client-defined identifier of the sampling location at a particular site.
MeasureName	Text	Description		Describes the measure being recorded.
MeasureQualifier Code	Text	Description		A code used to identify any qualifying issues that affect the results.
MeasureUnitCode	Limited List	Categorization		The code that represents the unit for measuring the item.
MeasureValue	Text	Description		The recorded dimension, capacity, quality, or amount of something ascertained by measuring or observing.
MethodCategory	Limited List	Categorization		The general class or common name for the group of substances being measured by a given method for the sample.
MethodCodeType	Limited List	Categorization		The published reference code of the method used by the laboratory to analyze the sample.
MethodDescription	Text	Description		A brief summary that provides general descriptive information about the method.
MethodIdentifier	Text	Identification	Report the WebEDR Method Identifier listed on the Method Profile.	The published, unique identifier (usually consisting of numbers or a combination of letters and numbers) for the method used by the laboratory to analyze the sample.
MethodLevel	Text	Description		The approximate level of substances in the sample, usually specified in client-defined concentration ranges and determined via a screening procedure.

Data Element	Format	Category	Business Rule	Definition
MethodModification Description	Text	Description		Text that identifies any modifications made to the published reference method.
MethodModification Identifier	Text	Identification		A client-defined identifier that identifies modifications made to the published reference method.
MethodName	Text	Description		The published name or title of the method used by the laboratory to analyze the sample.
MethodSource Name	Text	Description		The author or publishing agency of the method used by the laboratory to analyze the sample.
MethodType	Limited List	Categorization	Laboratories must always report the Client method, all other methods are optional.	A term that identifies the technology or method classification of the method used by the laboratory to analyze the sample.
MethodVersion	Text	Description		The version or revision of the method used by the laboratory to analyze the sample.
Organization Identifier	Text	Identification		The identifier associated with an organization (e.g., laboratory, client, subcontractor, etc.) performing a specific role in context of the project.
Organization LocationAddress	Text	Description		The primary street address of the location of the laboratory performing this analysis.
Organization LocationAddress City	Text	Description		The city in which the laboratory performing the analysis is located.
Organization LocationAddress Country	Text	Description		The country in which the laboratory performing the analysis is located.
Organization LocationAddress State	Text	Description		The state in which the laboratory performing the analysis is located.

Data Element	Format	Category	Business Rule	Definition
Organization LocationAddress ZipCode	Text	Description		The ZIP or postal code of the laboratory performing the analysis.
OrganizationMailing Address	Text	Description		The secondary address of the laboratory performing this analysis, if applicable. This would include additional address information (e.g., suite, maildrop, etc.).
OrganizationName	Text	Description		The name of an organization (e.g., laboratory, client, subcontractor, etc.) performing a specific role in context of the project.
Organization TelephoneNumber	Text	Description		The 10-digit telephone number of the laboratory performing the analysis.
OrganizationType	Text	Categorization		The role of the organization in context of the project.
PreparationBatch Identifier	Text	Association/ Grouping		A laboratory-defined identifier that is used to link multiple sample aliquots that are prepared together for analysis by one method. “Together” implies similarity of time, place, and manner of preparation.
PreparationEnd Date	Date	Date		The date (and times, if required) of the end of the preparation period for the sample aliquot, if the sample was prepared over a period of time.
PreparationStart Date	Date	Date		The date (and time, if required) of the preparation of this sample aliquot. Preparation is used generally to include method specific techniques such as extraction, digestion, and separation. If prepared over a range of dates, this is the start date.
PreparationType	Limited List	Categorization		A client-defined description used to define the specific preparation performed when multiple options are given within the referenced method.
Preservative	Text	Description		The chemical compound that was added to the sample to protect against decay or decomposition.
ProjectIdentifier	Text	Identification		A client-defined identifier for a project reporting a particular set of data. Typically, a project consists of samples from one site collected over some defined period of time.
ProjectName	Text	Description		A descriptive name or label for the project for which data is being reported for

Data Element	Format	Category	Business Rule	Definition
ReportingLimit	Text	Description		The reporting limit of the substance being measured. Reporting limits are defined in terms of a number below which data is typically reported as 'not detected' for the substance being measured.
ReportingLimitType	Limited List	Categorization		A term that identifies how the reporting limit was determined or reported.
ReportingLimit Units	Limited List	Categorization		Units for the reporting limit.
Result	Text	Result Measurement		The final calculated result for a substance accounting for all sample aliquot amounts, dilutions, moisture determinations, etc
ResultBasis	Text	Description		The basis upon which the final results were calculated.
ResultUncertainty	Numeric	Result Measurement		The estimated amount, expressed as a symmetric interval centered on the Result, by which the Result may differ from the true value due to all effects related to analysis of the sample aliquot by the laboratory.
ResultUnits	Limited List	Result Measurement		Units for the result.
RunBatchIdentifier	Text	Association/ Grouping		A laboratory-defined identifier that is used to link multiple analyses performed on one instrument and under the control of one initial calibration.
SampleChain of CustodyIdentifier	Text	Identification		A client-defined identifier for the chain of custody document and/ or tracking record associated with receipt of this sample in the laboratory.
SampleCollection EndDate	Date	Date		The date (and time, if required), of the end of the sample collection period, if the sample was collected over a period of time.
SampleCollection StartDate	Date	Date		The date (and time, if required) the sample was collected. If the sample was collected over a range of dates, this is the start date.
SampleDataGroup Type	Limited List	Categorization		Whether or not the data in this node is related to a preparation or cleanup activity.

Data Element	Format	Category	Business Rule	Definition
SampleIdentifier	Text	Identification	Report client identifier for field generated samples and laboratory identifier for laboratory or instrument samples.	A unique identifier assigned to a sample. This identifier should be what is assigned to the sample by the client. This element should always be reported. If reporting a laboratory generated sample then report the laboratories unique identifier for the sample.
SampleMatrix	Limited List	Categorization		An identifier of the general sample substrate or media.
SampleType	Limited List	Categorization		The client-defined term that identifies the specific type of sample being analyzed.
StorageBatch Identifier	Text	Association/ Grouping		A laboratory-defined identifier that is used to link multiple samples that are stored together in a defined period of time (e.g., samples stored in the same refrigerator or freezer).
SubstanceName	Limited List	Description		The published reference name for a substance
SubstanceType	Limited List	Categorization		A term that identifies the type of substance reported.

DET Valid Values

The following list details the values to which certain fields are limited within the DET. Valid values help ensure that automated processing can occur by providing a common language for important fields. Laboratories should only report a value in this list when reporting information for the data element that has a valid value list. Laboratories should use SEDD's valid value list as a reference for all valid values.

Table 8 DET Valid Values

Field	Valid Value
Analysis Type	Initial_Calibration, Average, MSA, Detection_Limit, Initial, Confirmation, Final
Organization Type	Customer, Laboratory, Sampler
Sample Data Group Type	Preparation, Cleanup
Exclusion Indicator	NO
Reporting Limit Type	CRRL, MDL, MDL_sa, IDL, LOD, LOD_sa, Ld, Ld_sa, ML, ML_sa, MRL, MRL_sa, Lc, Lc_sa, LCMRL, LCMRL_sa, LOQ, LOQ_sa, Lq, Lq_sa, PQL, PQL_sa, EQL, EQL_sa
Substance Type	Target, Spike, TIC, Internal_Standard, Surrogate, System_Monitoring_Compound, Monitor, Tracer, Instrument_Performance, Deuterated_Monitoring_Compound
Method Type	Client, Laboratory, Reference
SampleType	Cleanup_Blank, Duplicate, Field_Blank, Field_Duplicate, Field_Reagent_Blank, Field_Sample, Instrument_Blank, Laboratory_Control_Sample, Laboratory_Control_Sample_Duplicate, Laboratory_Duplicate, Laboratory_Fortified_Blank, Laboratory_Fortified_Blank_Duplicate, Laboratory_Fortified_Sample_Matrix, Laboratory_Fortified_Sample_Matrix_Duplicate, Laboratory_Performance_Check, Laboratory_Reagent_Blank, Matrix_Spike, Matrix_Spike_Duplicate, Matrix_Spiking_Solution, Method_Blank, Method_Instrument_Blank, Non-client_Sample, Performance_Evaluation_Sample, Post_Digestion_Spike, PT_Sample, Reagent_Blank, Serial_Dilution, Split_Samples, Storage_Blank, Storage_Blank, Trip_Blank, Baseline, Continuing_Calibration, Continuing_Calibration_Blank, Continuing_Calibration_Verification, Detection_Limit_Check_Standard, Florisil_Cartridge_Check, GPC_Calibration_Check, Initial_Calibration, Initial_Calibration_Blank, Initial_Calibration_Verification, Instrument_Performance_Check_PEM, Instrument_Performance_Check_Resolution, Instrument_Performance_Check_Tune, Interanalyte_Correction_Factor, Interference_Check_Standard_A, Interference_Check_Standard_A/B, Linear_Range_Verification, Quantitation_Limit_Check_Standard, ReslopeResolution_Check, Standard_Reference_Material, Calibration_Blank, Calibration_Standard, Continuing_Calibration_Check_Standard, Continuing_Calibration_Verification_Standard, End_Calibration_Check_Standard, Initial_Calibration_Check_Standard, Initial_Calibration_Standards, Instrument_Performance_Check_Solution, Tuning_Solution

Appendix D: XML Reporting Guide

The Data Exchange Template (DET) specifies the data necessary to include in an electronic submission, and XML is the format in which Type 2 will be provided. The following guide provides an overview of how the XML can be used to report a Type 2 electronic submission.

XML Syntax Guidelines

XML files must follow a specific structure and syntax so that other systems can read the contents. The following list provides general syntax rules that must be followed by every XML file:

- Non-empty elements are delimited by both a start-tag and an end-tag. (http://www.aphl.org/aphlprograms/eh/chemicals/drinkwater/Documents/EH_2010Jan_EPA_ERLNDataSubmissionsReq.pdf)
- Empty data elements can be reported, and if so, shall be indicated by a single tag indicating the data element name followed by a space and a forward slash and surrounded by angled brackets. Example: <SiteID />
- It is preferred that empty elements, for all but the required data elements, be left out of the file entirely so that only elements with data are reported. Required data elements must have values.
- Spaces are not allowed between opening and closing tags unless they are part of the data being reported for the element.
- Data element names are case-sensitive and shall be reported as described in the DET.
- Blank lines are allowed and can occur anywhere in the XML document. Blank lines can greatly improve the human readability factor of an XML file by providing visual separations in the data.
- Comment lines can occur anywhere in the XML document and are used to annotate the XML for human readers. Comment lines are usually displayed and printed by XML readers as they are not considered part of the data in the file. Comment lines are defined by angled brackets with the content surrounded by an exclamation mark and two dashes. Example: <!—Content is for samples from Site 1-->
- Data group and data elements names must exist in the DTD. Laboratories can report more data than required for a Type 2 data submission but the element must exist in the DTD and be reported in the correct data group. Laboratories cannot add new data groups or data elements to an XML document.
- Data elements cannot appear more than once within the same data group.
- The Type 2 DTD defines a particular order in which fields can be reported. XML files can have fewer fields than the DTD, but they must still appear in the same order. For example, in the SampleDetails data group the SampleIdentifier element is listed above the SampleMatrix element. This means that any Type 2 XML file that reports

SampleIdentifier and SampleMatrix must report them in this same order.

- The occurrence of a data group and/or data element within a DTD as well as the absence of a value can be defined in a DTD using XML syntax. The following is a list of syntax used throughout the Type 2 DTD to define how many times a data group can be reported as well as if a data element requires a value or if a value is optional.
    - ? data element or data group is not required and may only appear once under the parent data group that uses this reference. Example: Under the SampleDetails data group the SampleChainofCustodyIdenifier appears with a ? after it. This means this element does not have to be reported for this group but if it is, it can only appear once under the SampleDetails group.
    - * data element or data group is not required and may appear zero or more times under the parent data group that uses this reference. Example: The OrganizationDetails group defines its relationship with the PointofContacts group with an * meaning one organization can have 0 or more contacts reported under it.
    - + data element or data group is required and can appear more than one time under the parent data group that uses this reference. Example: The ProjectDetails group defines its relationship with the SampleDetails group with a + meaning the Project must have at least one sample reported but can have more than one.
    - No syntax after an element (Ex. SampleIdentifier,) – data element is required, must contain a value, and can only appear once under the parent data group that uses this reference.

Type 2 Data Hierarchy for Reporting

The Type 2 DET defines the data groups that organize the individual elements into groupings which in turn define the data. These groupings have inherent relationships and must be reported in a certain order to maintain the relationship in the XML document. The Type 2 DET uses a hierarchical relationship between most data groups, with the exception of Contact Information which has a relational relationship to several data groups. A hierarchical relationship means the placement of the data groups and data elements in the XML document defines the relationship of the content. A 'relational' relationship provides the ability to reference another data group by providing some form of an identifier, similar to how foreign keys in a database table function. Refer to Appendix C: Data Exchange Template (DET) for Type 2 for additional information regarding these groups.

In a DTD that primarily uses hierarchical relationships, there is a defined order in which data groups can be reported in a file. The following depicts the order in which data groups must be reported in a Type 2 XML document. The data groups that appear as subs to the primary level can be reported in any order as long as they are under their associated data group.

Type 2 Data Group Reporting Hierarchy:

1. ProjectDetails
2. OrganizationDetails
   a. PointOfContactDetails
3. MethodDetails
4. SampleDetails
   a. AnalysisDetails
      i. SamplePreparationDetails
      ii. SubstanceIdentificationDetails
         1. MeasureDetails
   b. CharacteristicDetails

Type 2 DTD Required Data Elements

The Type 2 DTD has defined a minimum list of required data elements based on the Type 1 requirements. By defining required fields in the DTD, Type 2 can ensure that data submitted contains the minimum amount of information necessary to identify the submission before the file is processed. Required elements are defined in the DTD by the lack of a character following a data element (Example: SampleIdentifier). The following is a list of the Type 2 DTD required fields. Note that a value must be present in every instance of these fields in order for a submission to successfully be uploaded into WebEDR, a free, web-based EPA data review package.

Table 9 DTD Required Data Groups

TYPE 2 Data Group	TYPE 2 Data Element
ProjectDetails	AnalyticalServiceRequestIdentifier
ProjectDetails	DataPackageIdentifier
ProjectDetails	ProjectIdentifier
OrganizationDetails	OrganizationIdentifier
SampleDetails	SampleIdentifier
SampleDetails	SampleMatrix
AnalysisDetails	MethodIdentifier
SubstanceIdentification Details	SubstanceName
MethodDetails	MethodIdentifier

The Type 2 DTD also defines required data elements when reporting optional data groups. The following list defines the conditionally required data elements for the Type 2 DTD.

Table 10 DTD Conditionally Required Data Groups

TYPE 2 Data Group	TYPE 2 Data Element
PointofContactDetails	ContactIdentifier
CharacteristicDetails	CharacteristicName
CharacteristicDetails	CharacteristicValue
MeasureDetails	MeasureName
MeasureDetails	MeasureValue

Appendix E: Type 2 Document Type Definition (DTD)

An XML DTD defines the building blocks of an XML document and is the most common way to specify an XML document. It defines the document structure with a list of legal elements and attributes. A DTD defines the structure of the XML document and validates the correctness of a file by providing the acceptable values for the document. The DTD provides laboratories with what their XML documents will be validated against and describes what should be reported.

The ERLN DTD is available electronically on the APHL website.

```
<?xml version="1.0" encoding="UTF-8"?>

<!--ERLN_General_1.DTD 07/07/2009-->

<!ELEMENT ProjectDetails (
                        AgreementModificationDescription?,
                        AgreementModificationIdentifier?,
                        AgreementNumber?,
                        AnalyticalServiceRequestIdentifier,
                        Comment?,
                        DataPackageIdentifier,
                        DataPackageName?,
                        DataPackageVersion?,
                        DateFormat?,
                        LaboratoryNarrative?,
                        LaboratoryQualifiersDefinition?,
                        LaboratoryReportedDate?,
                        ProjectIdentifier,
                        ProjectName?,
                        MethodDetails+,
                        OrganizationDetails+,
                        SampleDetails+
                        )>
<!ELEMENT MethodDetails (
                        Comment?,
                        MethodCategory?,
                        MethodCodeType?,
                        MethodDescription?,
                        MethodIdentifier,
                        MethodLevel?,
                        MethodModificationDescription?,
                        MethodModificationIdentifier?,
                        MethodName?,
                        MethodSourceName?,
                        MethodType?,
```

```
                    MethodVersion?
                    )>
<!ELEMENT OrganizationDetails (
                    Comment?,
                    OrganizationIdentifier,
                    OrganizationLocationAddress?,
                    OrganizationLocationAddressCity?,
                    OrganizationLocationAddressCountry?,
                    OrganizationLocationAddressState?,
                    OrganizationLocationAddressZipCode?,
                    OrganizationMailingAddress?,
                    OrganizationName?,
                    OrganizationTelephoneNumber*,
                    OrganizationType?,
                    PointofContactDetails*
                    )>
<!ELEMENT PointofContactDetails (
                    Comment?,
                    ContactElectronicAddress?,
                    ContactFullName?,
                    ContactIdentifier,
                    ContactTitle?,
                    ContactType?
                    )>
<!ELEMENT SampleDetails (
                    ContactIdentifier*,
                    LaboratoryReceiptDate?,
                    LaboratorySampleIdentifier?,
                    LocationIdentifier?,
                    Preservative?,
                    SampleChainofCustodyIdentifier?,
                    SampleCollectionEndDate?,
                    SampleCollectionStartDate?,
                    SampleIdentifier,
                    SampleMatrix,
                    SampleType?,
                    StorageBatchIdentifier?,
                    AnalysisDetails+,
                    CharacteristicDetails*
                    )>
<!ELEMENT AnalysisDetails (
                    AnalysisBatchIdentifier?,
                    AnalysisEndDate?,
                    AnalysisStartDate?,
```

```
                    AnalysisType?,
                    ContactIdentifier*,
                    InstrumentIdentifier?,
                    LaboratoryAnalysisIdentifier?,
                    LaboratoryFileIdentifier?,
                    MethodIdentifier,
                    PreparationBatchIdentifier?,
                    ResultBasis?,
                    RunBatchIdentifier?,
                     SamplePreparationDetails*,
                    SubstanceIdentificationDetails+
                    )>
<!ELEMENT SamplePreparationDetails (
                    CleanupBatchIdentifier?,
                    CleanupType?,
                    ContactIdentifier*,
                    MethodIdentifier?,
                    PreparationEndDate?,
                    PreparationStartDate?,
                    SampleDataGroupType?
                    )>
<!ELEMENT SubstanceIdentificationDetails (
                    CASRegistryNumber?,
                    ExclusionIndicator?,
                    ExpectedResult?,
                    ExpectedResultUnits?,
                    LaboratoryResultQualifier?,
                    LaboratorySubstanceIdentifier?,
                    ReportingLimit?,
                    ReportingLimitType?,
                    ReportingLimitUnits?,
                    Result?,
                    ResultUncertainty?,
                    ResultUnits?,
                    SubstanceName,
                    SubstanceType?,
                    MeasureDetails*
                    )>
<!ELEMENT CharacteristicDetails (
                    CharacteristicName,
                    CharacteristicType?,
                    CharacteristicUnits?,
                    CharacteristicValue,
                    Comment?
```

```
                    )>
<!ELEMENT MeasureDetails (
                    MeasureName,
                    MeasureQualifierCode?,
                    MeasureUnitCode?,
                    MeasureValue
                    )>
<!ELEMENT AgreementModificationDescription (#PCDATA)>
<!ELEMENT AgreementModificationIdentifier (#PCDATA)>
<!ELEMENT AgreementNumber (#PCDATA)>
<!ELEMENT AnalysisBatchIdentifier (#PCDATA)>
<!ELEMENT AnalysisEndDate (#PCDATA)>
<!ELEMENT AnalysisStartDate (#PCDATA)>
<!ELEMENT AnalysisType (#PCDATA)>
<!ELEMENT AnalyticalServiceRequestIdentifier (#PCDATA)>
<!ELEMENT CASRegistryNumber (#PCDATA)>
<!ELEMENT CharacteristicName (#PCDATA)>
<!ELEMENT CharacteristicType (#PCDATA)>
<!ELEMENT CharacteristicUnits (#PCDATA)>
<!ELEMENT CharacteristicValue (#PCDATA)>
<!ELEMENT CleanupBatchIdentifier (#PCDATA)>
<!ELEMENT CleanupType (#PCDATA)>
<!ELEMENT Comment (#PCDATA)>
<!ELEMENT ContactElectronicAddress (#PCDATA)>
<!ELEMENT ContactFullName (#PCDATA)>
<!ELEMENT ContactIdentifier (#PCDATA)>
<!ELEMENT ContactTitle (#PCDATA)>
<!ELEMENT ContactType (#PCDATA)>
<!ELEMENT DataPackageIdentifier (#PCDATA)>
<!ELEMENT DataPackageName (#PCDATA)>
<!ELEMENT DataPackageVersion (#PCDATA)>
<!ELEMENT DateFormat (#PCDATA)>
<!ELEMENT ExclusionIndicator (#PCDATA)>
<!ELEMENT ExpectedResult (#PCDATA)>
<!ELEMENT ExpectedResultUnits (#PCDATA)>
<!ELEMENT InstrumentIdentifier (#PCDATA)>
<!ELEMENT LaboratoryAnalysisIdentifier (#PCDATA)>
<!ELEMENT LaboratoryFileIdentifier (#PCDATA)>
<!ELEMENT LaboratoryNarrative (#PCDATA)>
<!ELEMENT LaboratoryQualifiersDefinition (#PCDATA)>
<!ELEMENT LaboratoryReceiptDate (#PCDATA)>
<!ELEMENT LaboratoryReportedDate (#PCDATA)>
<!ELEMENT LaboratoryResultQualifier (#PCDATA)>
<!ELEMENT LaboratorySampleIdentifier (#PCDATA)>
```

<!ELEMENT LaboratorySubstanceIdentifier (#PCDATA)>
<!ELEMENT LocationIdentifier (#PCDATA)>
<!ELEMENT MeasureName (#PCDATA)>
<!ELEMENT MeasureQualifierCode (#PCDATA)>
<!ELEMENT MeasureUnitCode (#PCDATA)>
<!ELEMENT MeasureValue (#PCDATA)>
<!ELEMENT MethodCategory (#PCDATA)>
<!ELEMENT MethodCodeType (#PCDATA)>
<!ELEMENT MethodDescription (#PCDATA)>
<!ELEMENT MethodIdentifier (#PCDATA)>
<!ELEMENT MethodLevel (#PCDATA)>
<!ELEMENT MethodModificationDescription (#PCDATA)>
<!ELEMENT MethodModificationIdentifier (#PCDATA)>
<!ELEMENT MethodName (#PCDATA)>
<!ELEMENT MethodSourceName (#PCDATA)>
<!ELEMENT MethodType (#PCDATA)>
<!ELEMENT MethodVersion (#PCDATA)>
<!ELEMENT OrganizationIdentifier (#PCDATA)>
<!ELEMENT OrganizationLocationAddress (#PCDATA)>
<!ELEMENT OrganizationLocationAddressCity (#PCDATA)>
<!ELEMENT OrganizationLocationAddressCountry (#PCDATA)>
<!ELEMENT OrganizationLocationAddressState (#PCDATA)>
<!ELEMENT OrganizationLocationAddressZipCode (#PCDATA)>
<!ELEMENT OrganizationMailingAddress (#PCDATA)>
<!ELEMENT OrganizationName (#PCDATA)>
<!ELEMENT OrganizationTelephoneNumber (#PCDATA)>
<!ELEMENT OrganizationType (#PCDATA)>
<!ELEMENT PreparationBatchIdentifier (#PCDATA)>
<!ELEMENT PreparationEndDate (#PCDATA)>
<!ELEMENT PreparationStartDate (#PCDATA)>
<!ELEMENT Preservative (#PCDATA)>
<!ELEMENT ProjectIdentifier (#PCDATA)>
<!ELEMENT ProjectName (#PCDATA)>
<!ELEMENT ReportingLimit (#PCDATA)>
<!ELEMENT ReportingLimitType (#PCDATA)>
<!ELEMENT ReportingLimitUnits (#PCDATA)>
<!ELEMENT Result (#PCDATA)>
<!ELEMENT ResultBasis (#PCDATA)>
<!ELEMENT ResultUncertainty (#PCDATA)>
<!ELEMENT ResultUnits (#PCDATA)>
<!ELEMENT RunBatchIdentifier (#PCDATA)>
<!ELEMENT SampleChainofCustodyIdentifier (#PCDATA)>
<!ELEMENT SampleCollectionEndDate (#PCDATA)>
<!ELEMENT SampleCollectionStartDate (#PCDATA)>

```
<!ELEMENT SampleDataGroupType (#PCDATA)>
<!ELEMENT SampleIdentifier (#PCDATA)>
<!ELEMENT SampleMatrix (#PCDATA)>
<!ELEMENT SampleType (#PCDATA)>
<!ELEMENT StorageBatchIdentifier (#PCDATA)>
<!ELEMENT SubstanceName (#PCDATA)>
<!ELEMENT SubstanceType (#PCDATA)>
```

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