THE ROLE OF DATA USABILITY ASSESSMENT IN DATA QUALITY

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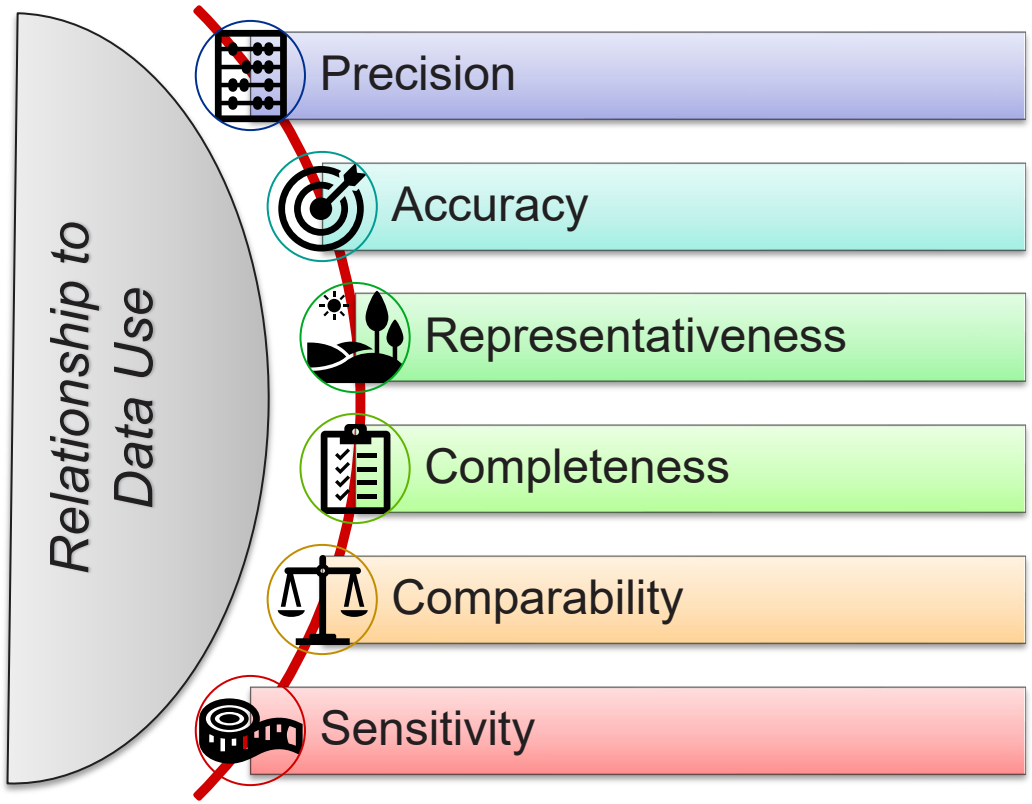
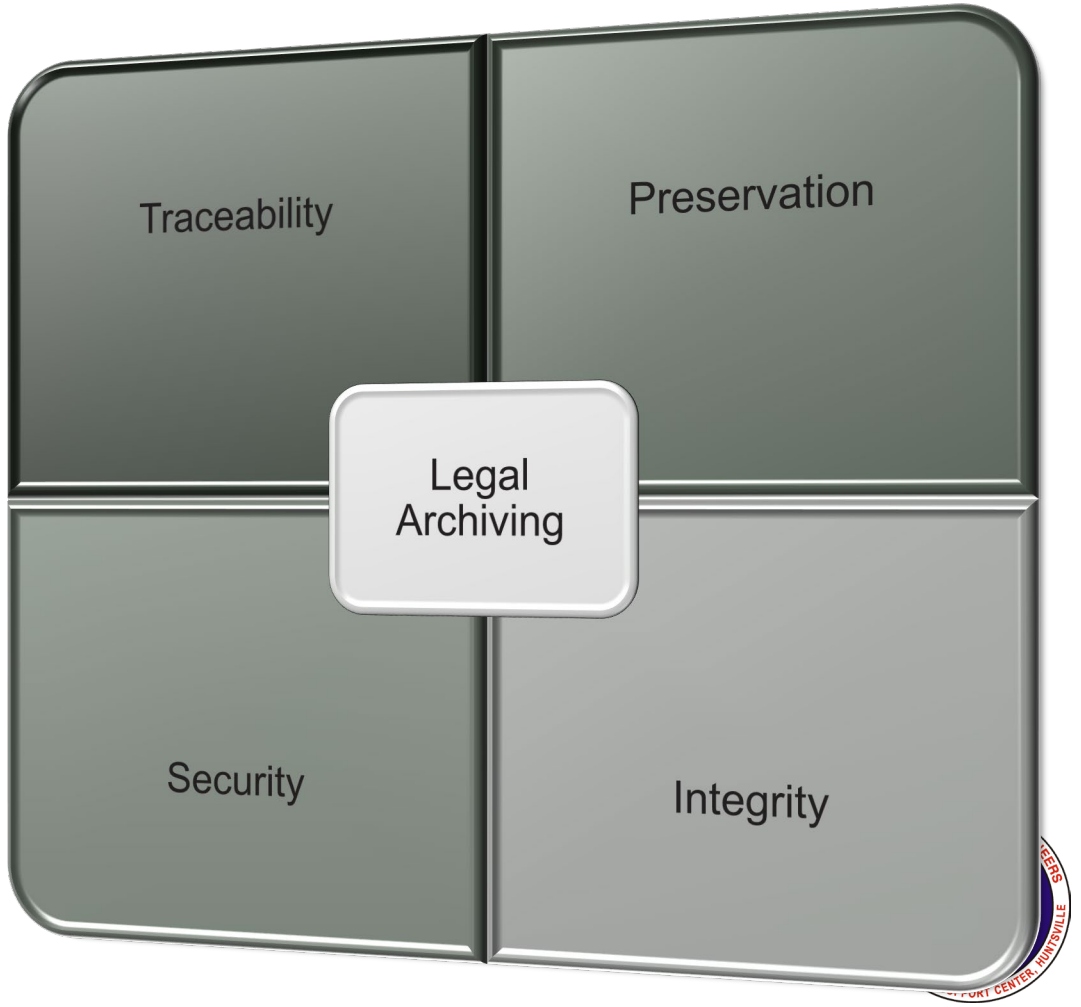
US Army Corps of Engineers®

DATA COLLECTION GOALS – BIG PICTURE

Scientifically Valid



Legally Defensible



ROADMAP

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- Start with Systematic Project Planning
- Importance of careful data collection
- Determining appropriate data review
- Performing a thorough Data Usability Assessment
- Ensuring complete documentation
- Examples

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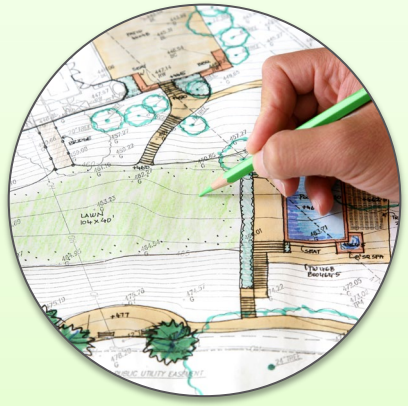
PROJECT LIFE CYCLE

Project Identification



Systematic Project Planning and QAPP Development

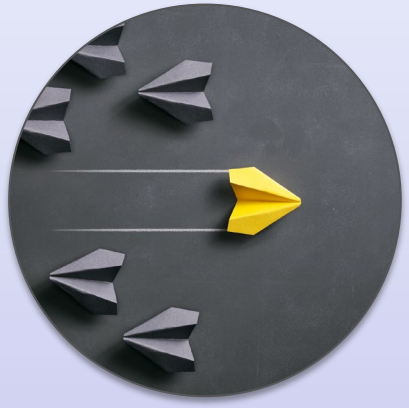
- Scoping Sessions/ Define Problem
- Identify Data Quality Objectives (DQOs)
- Develop sampling design to meet DQOs
- Determine Measurement Performance Criteria (MPCs) to meet DQOs

Field and Lab Activities

- Collection of Samples and field analyses
- Laboratory Sample and QC Analyses
- Laboratory Data Deliverables

Data Review Activities

- Data Verification
- Data Validation
- Data Usability Assessment



Use data to make site decisions

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PROJECT LIFE CYCLE

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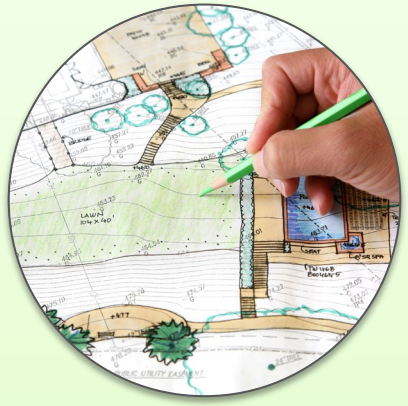

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PLANNING FOR DATA QUALITY

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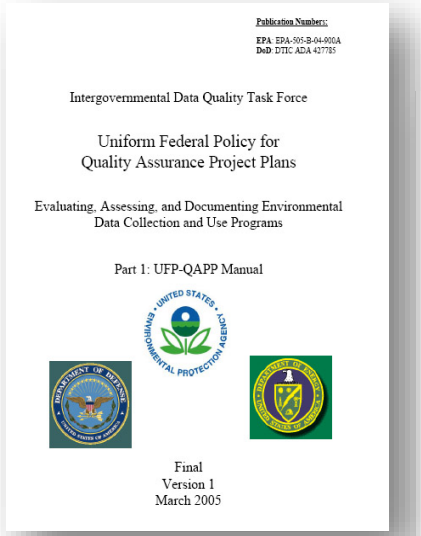
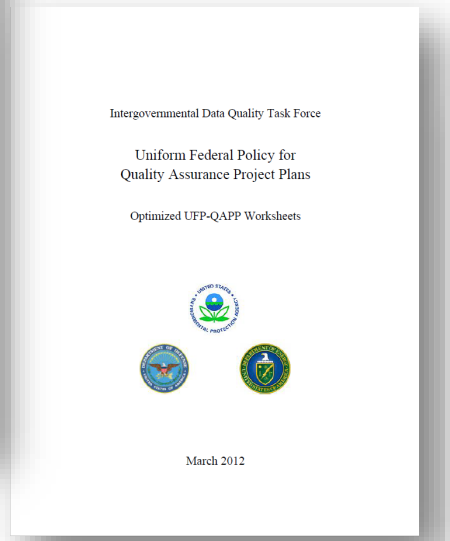
Starts with Systematic Planning Process and the UFP-QAPP Worksheets

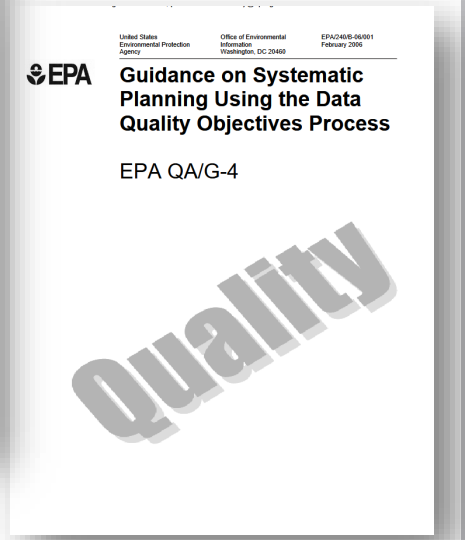
- WS #1-8, Management: Background, PDT, Communication Pathways, Training Requirements, Proof of Review, and Approval Pages
- WS #9, Planning Sessions: Documents ALL project meetings and agreements
- WS #10-16, Project Objectives: CSM & DQO Development, and Performance Objectives
- WS #17-30, Design and Data Collection: Sampling and Analysis Methods, and Quality Control Requirements
- WS #31-33, Assessment and Oversight
- WS #34-37, Data Review

A Few References

- Uniform Federal Policy for Quality Assurance Project Plans, Part 1: UFP-QAPP Manual (2025)
- Uniform Federal Policy for Quality Assurance Project Plans, Optimized Worksheets (2012)
- EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4 (2006)







DQO PROCESS OVERVIEW

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1. State the Problem — What is the problem we need to solve?
- Define the problem that necessitates the study; identify the planning team, examine budget, schedule

2. Identify the Goal of the Study — What are we trying to do about it?
- State how environmental data will be used in meeting objectives and solving the problem, identify study questions, define alternative outcomes

3. Identify Information Inputs — What data do we need to address the questions in 1 and 2?
- Identify data & information needed to answer study questions

4. Define the Boundaries of the Study — What limitations are we working under?
- Specify the target population & characteristics of interest, define spatial & temporal limits, scale of inference

5. Develop the Analytic Approach — What are we going to do with the data (decision rules)?
- Define the parameter of interest, specify the type on inference, and develop the logic for drawing conclusions from findings
- Determine whether to use Hypothesis testing (decision making) or Estimation Approach

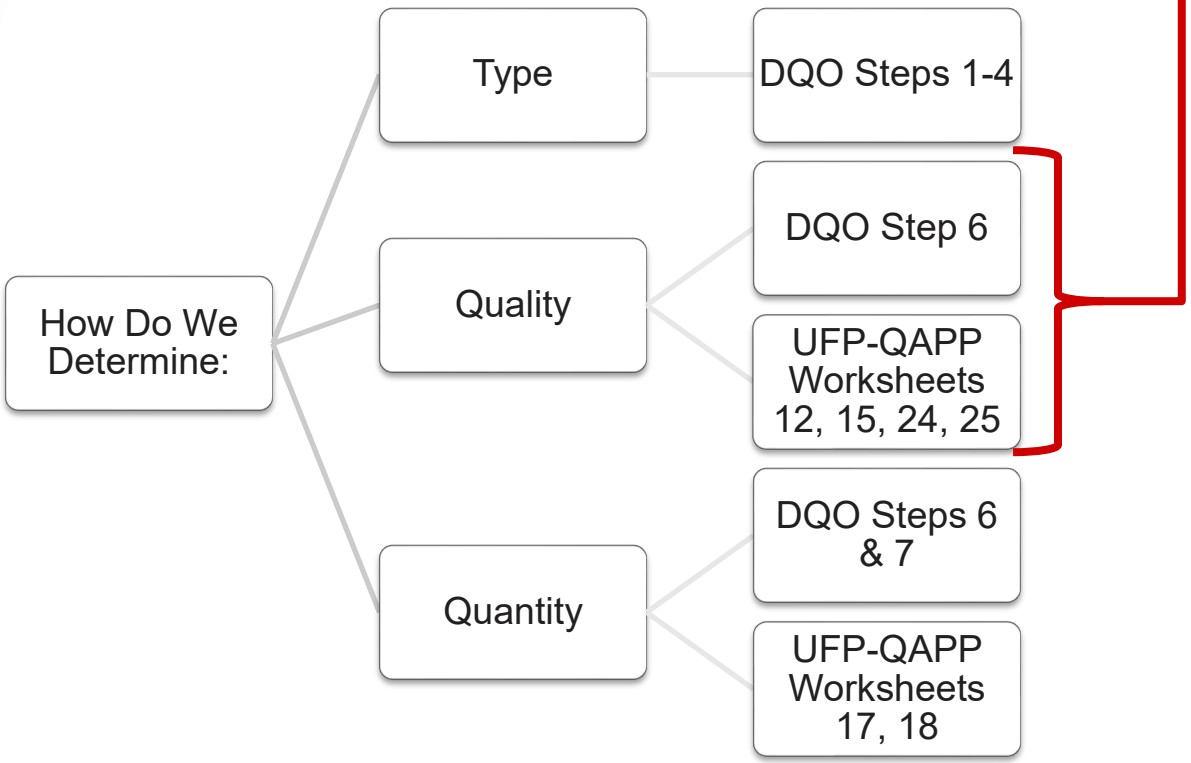
6. Specify Performance or Acceptance Criteria — How certain do we need to be about our decision?
- Specify probability limits for false rejection and false acceptance decision errors (for hypothesis testing)
- Develop performance criteria for new data being collected or acceptable criteria for existing data being considered for use (for estimation problems)

7. Develop the Plan for Obtaining Data — Given all the above, how are we going to do this?
- Select the resource-effective sampling and analysis plan that meets the performance criteria

[1] Guidance on Systematic Planning Using the Data Quality Objectives Process, U.S. EPA, EPA QA/G-4, February 2006.

WHERE DO PARCCS AND DATA QUALITY TARGETS COME FROM?

In order to make defensible decisions at our sites, our data must be of the **right type, quality, and quantity.** Where does that determination come from?



Key Takeaways about Data Quality

Parameter	Evaluation for individual data points (MPC)	Evaluation for a data set (DQO)
Precision	Field duplicates, laboratory duplicates, matrix spike duplicates, analytical replicates, surrogates	Population parameters (e.g., standard deviation of all samples)
Accuracy	PT samples, matrix spikes, laboratory control samples, equipment blanks	Comparison of achieved certainty to predicted certainty (DQO step 6 and DUA step 3-5)
Representativeness	Sampling SOPs, field replicates	Sampling Design (DQO Step 7), achieved variance of all samples
Comparability	Split samples, comparison of different sampling or analytical methods	Statistical correlations or comparison of data sets
Completeness	Number of samples/ analyses received vs. planned	Comparison of achieved certainty to predicted certainty (DQO step 6 and DUA step 3-5)
Sensitivity	Laboratory detection limits, limits of detection, limits of quantitation	Proximity of measure of central tendency to action levels along with measures of variance

WHERE DOES DATA QUANTITY TARGET COME FROM?

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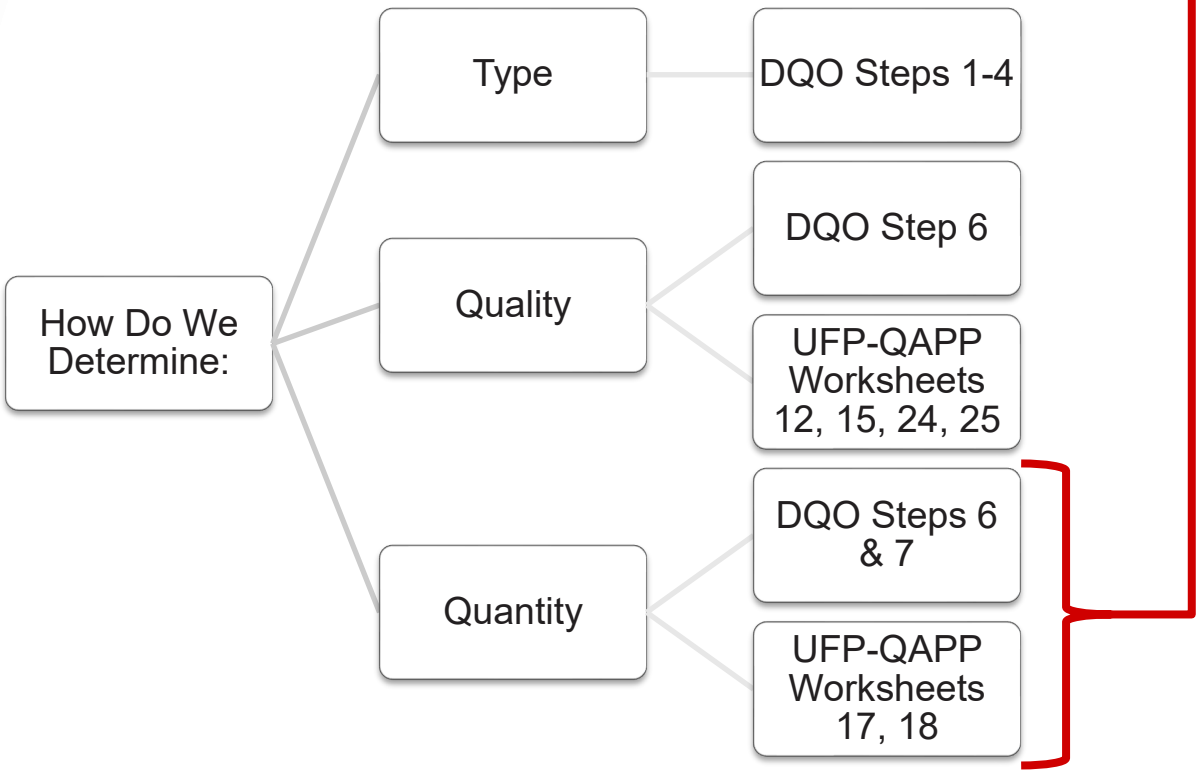

Key Takeaways about Sampling Design

- Know the differences between statistical and judgmental sampling. Remember, you can't know the accuracy or bias of a result from a judgmental sampling design.
- When attempting to make a robust comparison to an action level, a statistical sampling design is the only way to understand the certainty of that determination.
- Developing a robust sampling design is easier than it seems with a few simple tools.
- The key inputs will be:
  - Population parameter of interest (DQO step 5)
  - Appropriate action level for comparison (DQO step 5)
  - Boundaries on the "gray region" (DQO step 5)
  - How well you want to control for decision errors (DQO step 5)
  - Estimate of anticipated sampling and analytical variability (talk to the chemist)

PROJECT LIFE CYCLE

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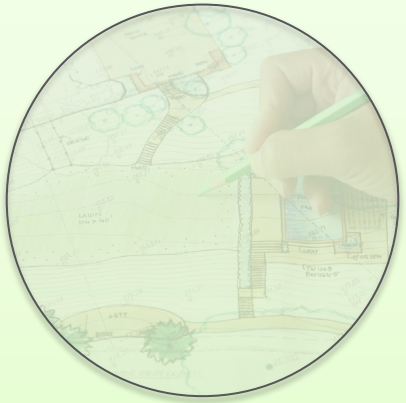

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Use data to make site decisions

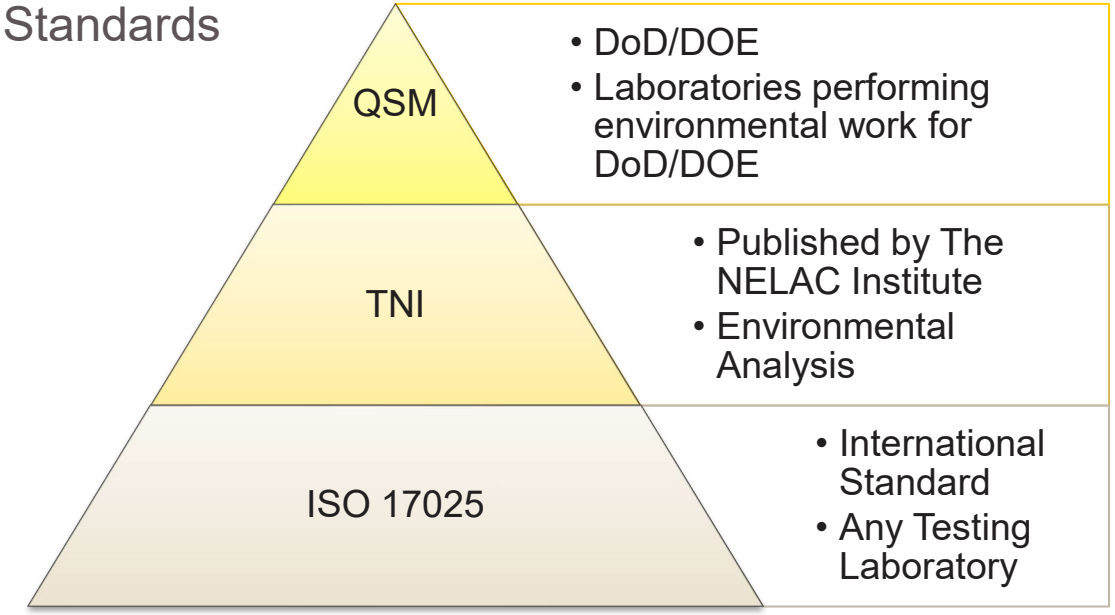
DATA QUALITY – EXECUTION

Field Activities

- Adherence to Sampling Plan
- Following field SOPs
- Field QC samples (e.g., field blanks, field replicates, etc.)
- Field Measurement QA/QC including instrument calibration and standards

Laboratory Activities

QSM - Published by EDQW, built upon ISO and TNI Standards



- Minimum quality requirements for laboratories performing environmental analysis for DoD/DOE
- Accreditation by approved third-party ABs
- Does not provide sampling requirements
- Does not ensure specific data points have met requirements or that data are usable for a project

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PROJECT LIFE CYCLE

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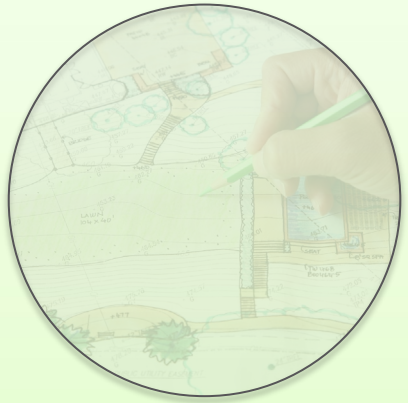

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DATA REVIEW PROCESS

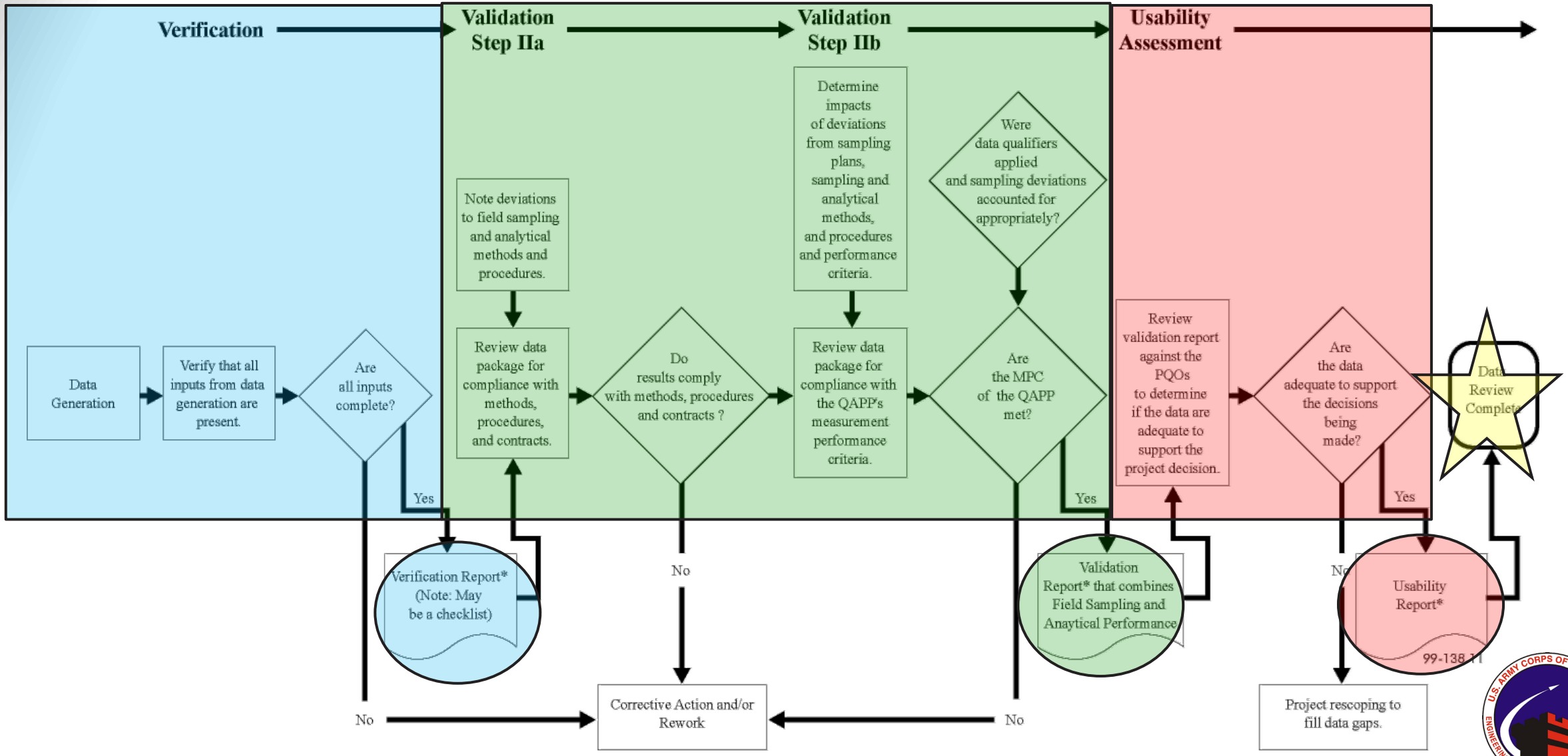

Figure from IDQTF, UFP-QAPP Manual V1, March 2005, Figure 37. Data Review Process.

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WHAT'S THE DIFFERENCE?

	Verification	Validation	Usability Assessment
Purpose	Ensure presence and completeness	Ensure compliance with underlying specifications (e.g.., SOPs, Published Methods, Quality Systems Manual)	Adequate quality and quantity for decisions (DQOs, PARCCS)
Responsible Party	Varies, usually a prime contractor	3rd Party Validators*	Entire Project Team
Covers	All project records including field and laboratory data	Laboratory Data (should include other data that affects decision quality)	All project records and data
Timeline	Following data collection/generation activity	Following laboratory report issuance	End of sampling event, prior to decision making

DATA VALIDATION

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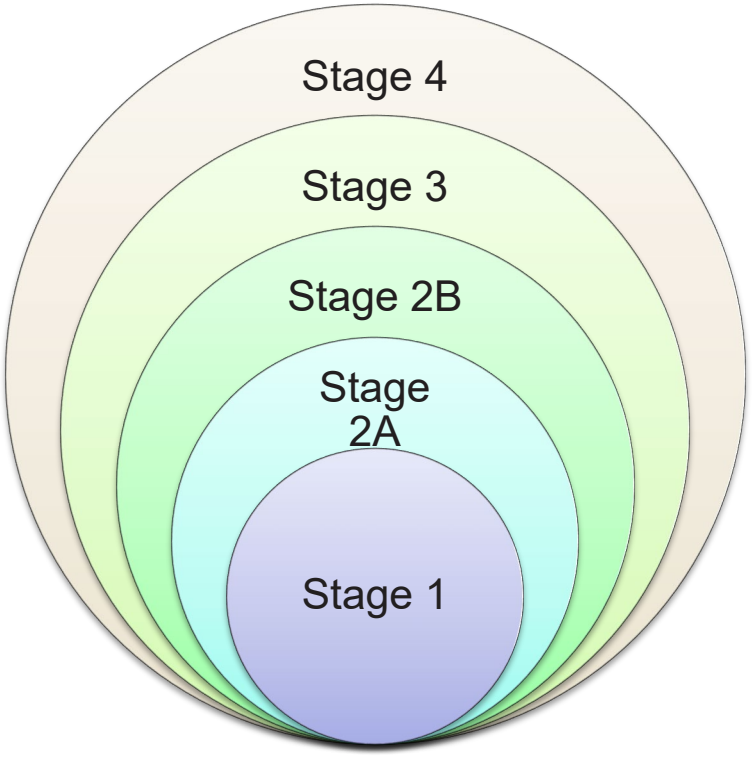
Stages of Data Validation

Stage 1:
- Sample results forms
- Sample receipt summaries
- Field QC data

Stage 2A and 2B:
- Batch- and Sample-Specific QC
- Instrument QC
- Summary forms only

Stage 3 and 4:
- Review of raw data
- Recalculation of a subset of data



Which Stage is Right for my Project?

- Depends on Project DQOs
- Remember, a higher stage of validation does not necessarily result in higher data quality
- Higher stages of validation give us more confidence in the conformance of the data to the specifications

DATA VALIDATION REPORT

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- Prepared by validator following completion of validation
- Identifies laboratory SDGs, analyses included
- Includes cross reference between field sample identification and laboratory sample identification
- Specifies procedures followed including validation stage and percent recalculation
- Data is associated with a “validation qualifier”

Data Validation Report

- Cover Letter and Introduction
- Findings
- Checklists
- Documentation of recalculations
- Annotated Laboratory Reports
- Acronyms and Abbreviations
- Data Qualifiers Reference Table
- EDDs

Qualifier	Definition
U	The analyte was not detected above the associate value (e.g., 5 U is synonymous with <5).
J	The reported result is an estimated value with unknown bias.
J+	The reported result is an estimated value and may be biased high.
J-	The reported result is an estimated value and may be biased low.
N	The analysis indicates the presence of an analyte for which there was presumptive evidence to make a tentative identification.
NJ	The analyte has been “tentatively identified” or “presumptively” as present and the associated numerical value is estimated.
UJ	The analyte was not detected; however, the associated numerical value is approximate.
X	The sample results were affected by serious deficiencies. Presence or absence of the analyte cannot be substantiated by data provided. Exclusion of data is recommended.

SOME COMMENTS ON THE X QUALIFIER

"It should be re-emphasized that it is not the role of data validation to determine if project goals have been met or to provide the decisions to be made. Data validation provides the overall appraisal of a data set and the project team should use this appraisal along with their own judgment when making decisions. It is not the role of data validation to accept or reject data. As such, the conventional R (reject) flag has been removed from this document. The project team should make the decision to accept or reject qualified data during the Data Usability stage, in accordance with the QAPP (for example, using the process described in UFP-QAPP Worksheet #37)."

Then who does reject data and when?

Time to talk about Data Usability

ASSEMBLING THE PDT

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Entities

Lead Organization/USACE

Stakeholders/Regulators

Contractor

Subcontractors

Each entity brings their own personnel and subject matter experts (SMEs) to the table

Personnel

- Project Managers
- Technical Managers
- Resource Managers
- Geologists
- Hydrogeologist
- Geophysicists
- Risk Assessors
- Chemists
- Statisticians
- Analysts
- Field Samplers
- Safety Personnel

Look for ways to maximize these resources and collaborate with a common goal of protecting human health and the environment through decisions based on legally defensible data of known quality

RESPONSIBILITIES

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Government Personnel

Government Project Manager

- Directs, oversees, and coordinates all project activities for the lead organization including the execution of the DUA
- Ensures all technical issues are satisfactorily addressed

Government Technical Manager

- Participates in DUA, brings documentation produced and reviewed during project activities to the table
- Provides a broad technical viewpoint to help put data in context of questions being asked and activities that took place

Government SMEs

- Participates in DUA, brings documentation produced and reviewed during project activities to the table
- Provides expertise needed to review each aspect of data collected, perform the appropriate analysis, and draw conclusions about both quality and meaning of the data

Contractor Personnel

Project Manager, Technical Managers, and SMEs:

- Participates in DUA, brings documentation produced and reviewed during project activities
- Provides a broad project viewpoint to help put data in context
- Provides expertise needed to review each aspect of data collected, perform the appropriate analysis, and draw conclusions about both quality and meaning of the data

Field, Safety, and QA Oversight Personnel

- Provides documentation & findings produced during project activities
- Participate in DUA on an as needed basis

Regulator and Stakeholder Responsibilities

- Participates in DUA to varying extents
- Provides a broad regulatory viewpoint to help put data in context of questions being asked and activities that took place

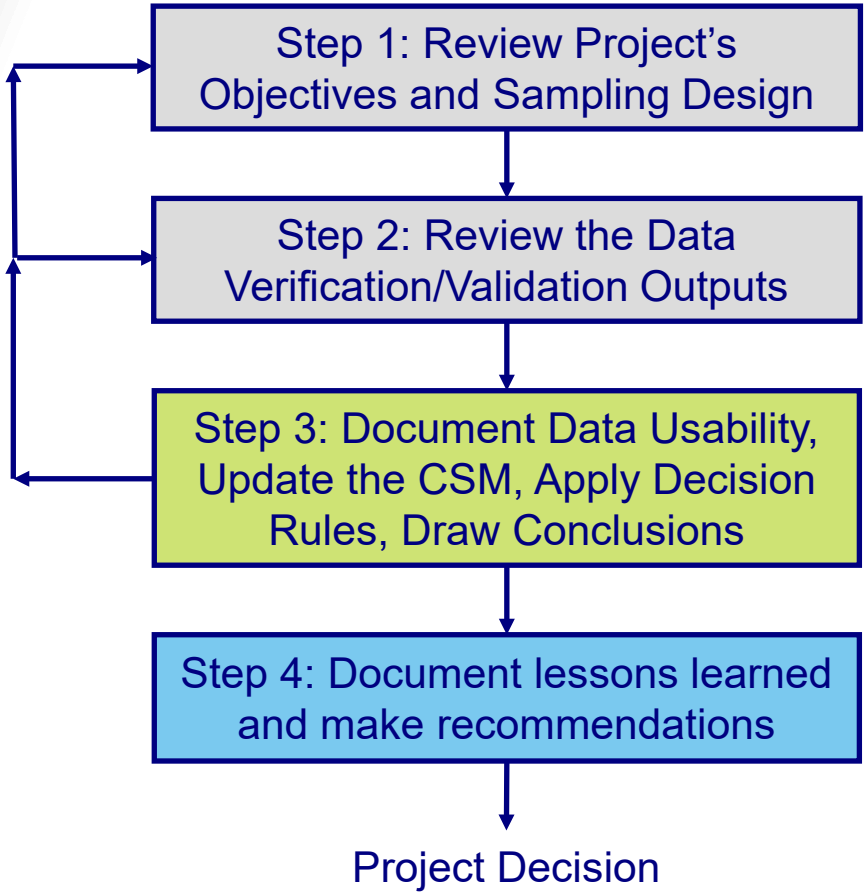
Note: Regulator participation early in the DUA process is highly encouraged. Consider scheduling meetings or communicating via email while DUA steps are being conducted or provide an early draft for comment prior to submitting the project report for review.

LOGISTICS OF DUA MEETING

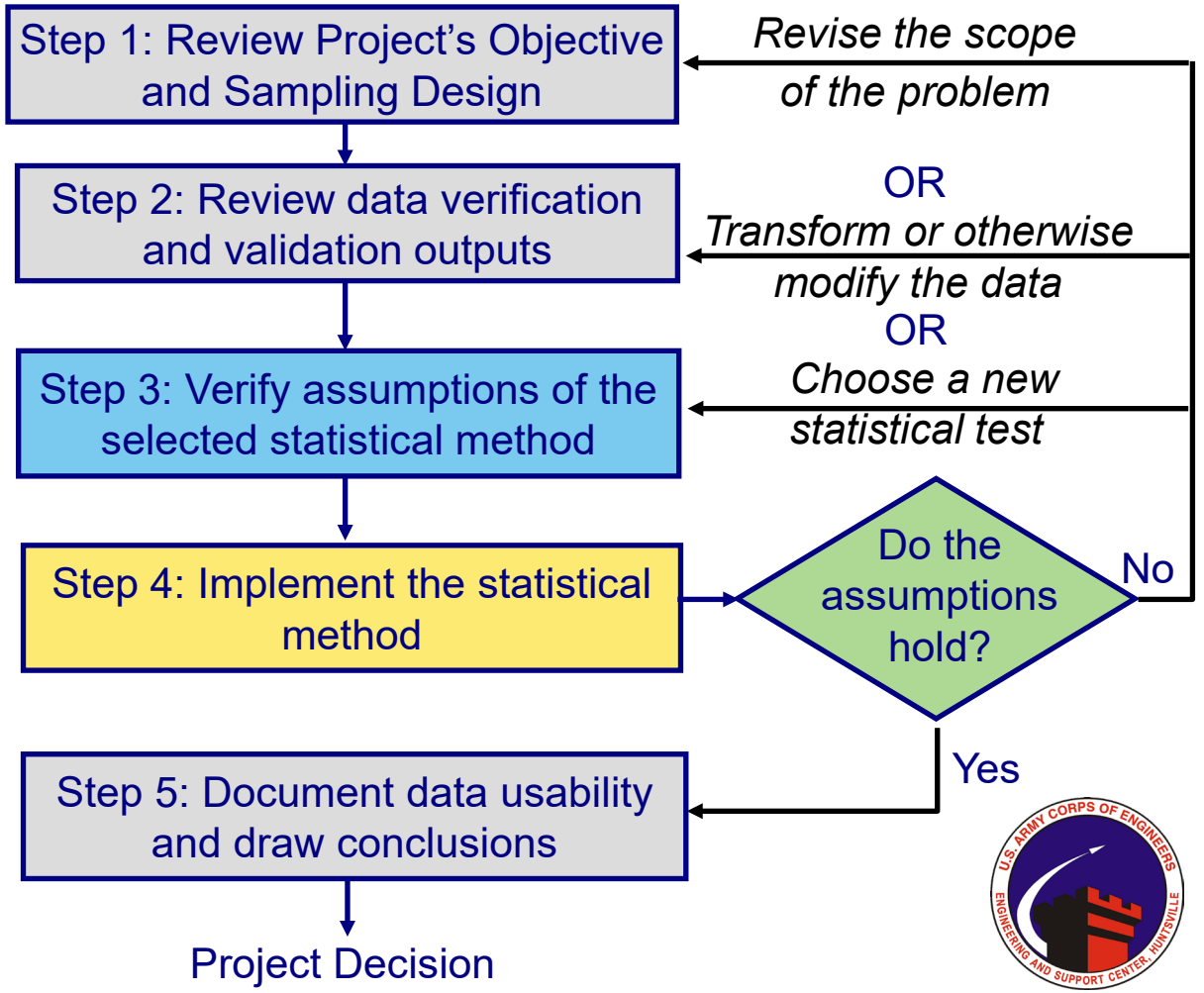
In Person	Virtual – Real Time	Virtual – Asynchronous
• Government PM, with contractor schedules, hosts, and facilitates DUA meeting • Recorder documents responses to questions and distributes draft for review	• Government PM with contractor schedules, hosts, and facilitates teleconference • Recorder documents responses to questions and distributes draft for review	• Designated POC may send out email request for feedback on DUA Steps/ Questions • POC assembles responses and distributes draft for review

DUA PROCESS – MR-QAPP AND UFP-QAPP

IDQTF, MR-QAPP Munitions Response Toolkit Module 1, April 2020 WS #37



IDQTF, Optimized UFP-QAPP Worksheets, March 2012 WS #37



DUA STEP 1 – REVIEW THE PLAN

Step 1	Review the project's objectives and sampling design Review the key outputs defined during systematic planning (i.e.,PQOs or DQOs and MPCs) to make sure they are still applicable. Review the sampling design for consistency with stated objectives. This provides the context for interpreting the data in subsequent steps.

Revisit the planning – What were we trying to do?

- Review the Conceptual Site Model and any new or contradictory information (Worksheet 10)
- Was the problem statement correct? (DQO Step 1)
- Were study questions complete? (DQO Step 2)
- Were all necessary data inputs identified? (DQO Step 3)
- Were study boundaries (spatial and temporal) adequately defined? (DQO Step 4)
- Was the data collection approach appropriate to address the problem statement and study questions? Were decision rules specified? Were alternative outcomes and their consequences clearly explained? (DQO Step 5)
- Were MPCs sufficient to address DQO Steps 1-5 and ensure the satisfaction of all data quality indicators? (DQO Step 6)
- Did the sampling design address all MPCs? Were data reduction procedures and statistical methods specified and relevant to the problem statement? Was data reduction performed in accordance with specifications? Can the data be used as intended? (DQO Step 7)

STEP 2 – REVIEW DATA

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Step 2	Review the data verification and data validation outputs Review available QA reports, including the data verification and data validation reports. Perform basic calculations and summarize the data (using graphs, maps, tables, etc.). Look for patterns, trends, and anomalies (i.e., unexpected results). Review deviations from planned activities (e.g., number and locations of samples, holding time exceedances, damaged samples, non-compliant PT sample results, and SOP deviations) and determine their impacts on the data usability. Evaluate implications of unacceptable QC sample results.

Review ALL the data – What did we do?

- Collect field, laboratory, and appropriate historical data.
- Were Measurement Performance Criteria (MPC) achieved?
- Were appropriate MPCs referenced during validation?
- Were all field procedures followed?
- Was the impact of all non-conformances on individual data points adequately explained?
- What are the impacts to the PARCCS parameters on the data set as a whole?

STEP 3 AND 4 – DO THE MATH

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Step 3	**Verify the assumptions of the selected statistical method** Verify whether underlying assumptions for selected statistical methods (if documented in the QAPP) are valid. Common assumptions include the distributional form of the data, independence of the data, dispersion characteristics, homogeneity, etc. Depending on the robustness of the statistical method, minor deviations from assumptions usually are not critical to statistical analysis and data interpretation. If serious deviations from assumptions are discovered, then another statistical method may need to be selected.

Review plan for data analysis

- What calculations or comparisons were intended?
- Do those calculations rely on specific underlying requirements of the data set (e.g., normal distribution, sample set homogeneity, etc.)? If so, does the data set conform to those requirements?
- If the intended statistical test or comparison is no longer valid, consult a statistician to select a new one.

Step 4	**Implement the statistical method** Implement the specified statistical procedures for analyzing the data and review underlying assumptions. For decision projects that involve hypothesis testing (e.g., "concentrations of lead in groundwater are below the action level") consider the consequences for selecting the incorrect alternative; for estimation projects (e.g., establishing a boundary for surface soil contamination), consider the tolerance for uncertainty in measurements.

Analyze the data

- Carry out the calculations or comparisons and state the result(s) with level of certainty.

STEP 5 – DOCUMENT THE DECISIONS

Step 5	**Document data usability and draw conclusions** Determine if the data can be used as intended, considering implications of deviations and corrective actions. Discuss data quality indicators. Assess the performance of the sampling design and Identify limitations on data use. Update the conceptual site model and document conclusions. Prepare the data usability summary report which can be in the form of text and/or a table.

Document process and state conclusions – traceability and clear determinations

- Were any sample level lessons learned identified?
- Were any event level lessons learned identified?
- Were any project level lessons learned identified?
- Were any program level lessons learned identified?

Prepare the data usability report

DUA REPORT

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Historical Perspective

How many of you have seen a DUA documentation paragraph that looks like this?

One hundred percent of the data generated are suitable for their intended use. No systematic accuracy or precision trends were identified. No sample results were rejected. Samples results that were qualified as estimated are usable for project decisions. The completeness goals for the required type of samples requirements were met.

Based on this paragraph, can you tell which DUA questions were evaluated and how the data relate to the project context/problem?

Try this instead

Data Usability Assessment Report

- Document the DUA steps
- State the data reviewed
- Discuss the deviations from MPC and their impact to the decision
- Clearly state the conclusions and decisions with the associated certainty
- Demonstrate how the conclusions follow scientifically from the data collected
- Include the full DUA report as an appendix and reference as needed

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PROJECT LIFE CYCLE

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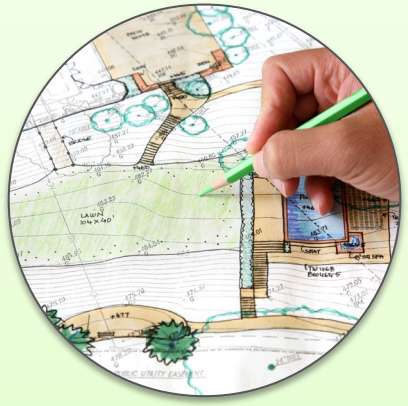

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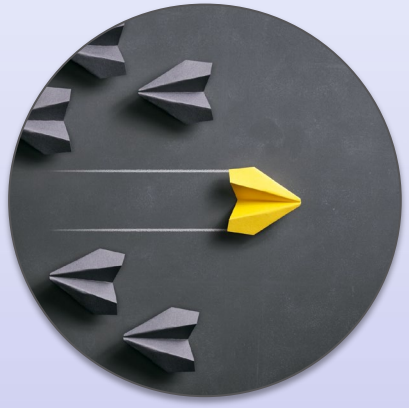

Use data to make site decisions

LET'S LOOK AT AN HTRW EXAMPLE

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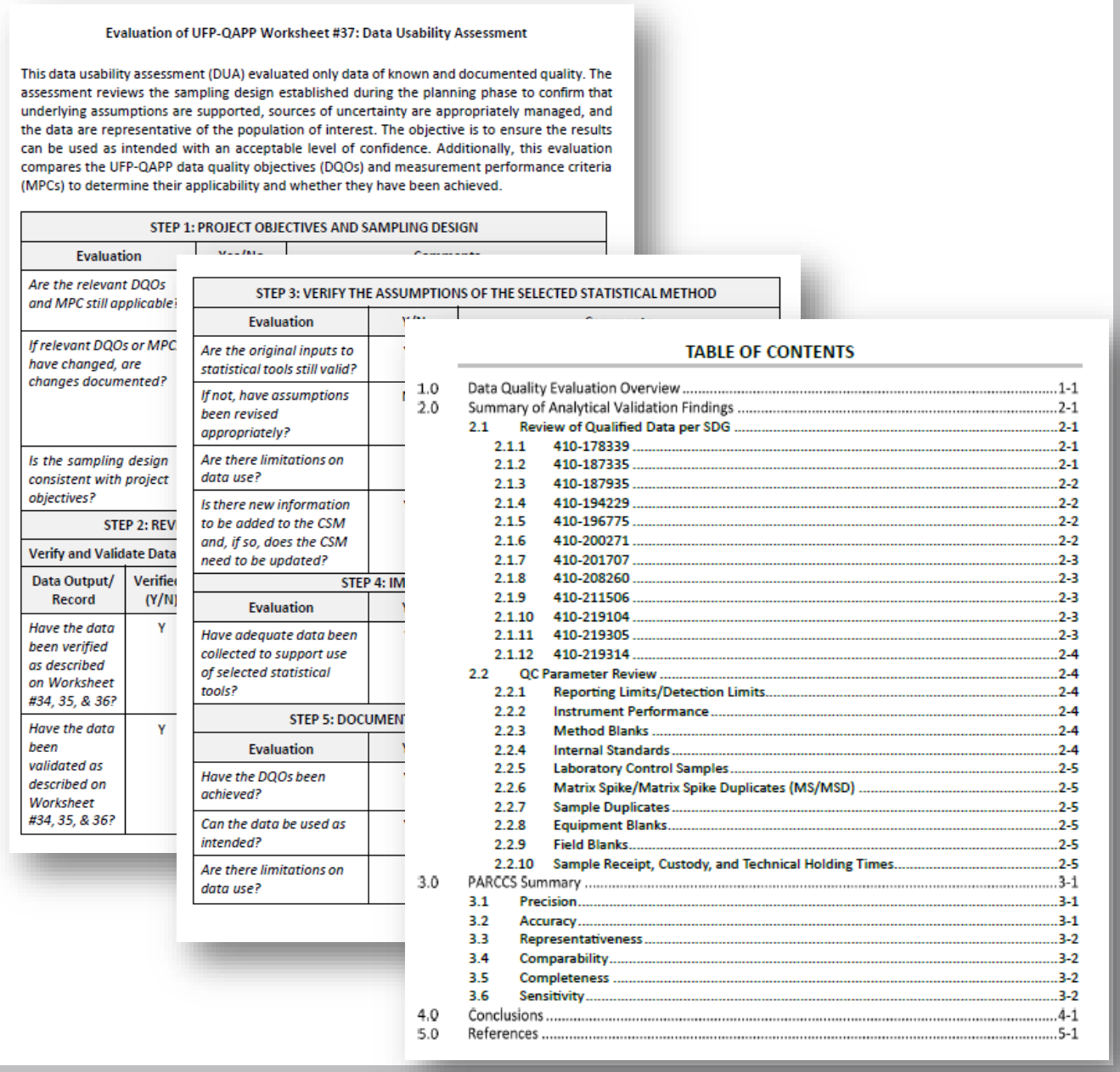
HTRW Remedial Investigation Report

DUA Evaluation Appendix

- Clearly addresses each of the 5 DUA steps
- Incorporates in-depth discussion through reference to in-depth discussion

In-Depth Discussion Appendix

- Clearly discusses the validation findings and impacts on data (section 2)
- Specifically addresses each of the PARCCS parameters as related to project DQOs (Section 3)
- Has concise conclusion stating site decisions (Section 4)



Evaluation of UFP-QAPP Worksheet #37: Data Usability Assessment

This data usability assessment (DUA) evaluated only data of known and documented quality. The assessment reviews the sampling design established during the planning phase to confirm that underlying assumptions are supported, sources of uncertainty are appropriately managed, and the data are representative of the population of interest. The objective is to ensure the results can be used as intended with an acceptable level of confidence. Additionally, this evaluation compares the UFP-QAPP data quality objectives (DQOs) and measurement performance criteria (MPCs) to determine their applicability and whether they have been achieved.

STEP 1: PROJECT OBJECTIVES AND SAMPLING DESIGN

Evaluation	Yes/No	Comments
Are the relevant DQOs and MPC still applicable?		
If relevant DQOs or MPC have changed, are changes documented?		
Is the sampling design consistent with project objectives?		

STEP 2: REV

Verify and Validate Data

Data Output/ Record	Verifie (Y/N)
Have the data been verified as described on Worksheet #34, 35, & 36?	Y
Have the data been validated as described on Worksheet #34, 35, & 36?	Y

STEP 3: VERIFY THE ASSUMPTIONS OF THE SELECTED STATISTICAL METHOD

Evaluation	
Are the original inputs to statistical tools still valid?	
If not, have assumptions been revised appropriately?	
Are there limitations on data use?	
Is there new information to be added to the CSM and, if so, does the CSM need to be updated?	

STEP 4: IM

Evaluation	
Have adequate data been collected to support use of selected statistical tools?	

STEP 5: DOCUMEN

Evaluation	
Have the DQOs been achieved?	
Can the data be used as intended?	
Are there limitations on data use?	

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LET'S LOOK AT AN MMRP EXAMPLE

U.S. ARMY

MMRP Remedial Investigation Report

DUA Evaluation Summary

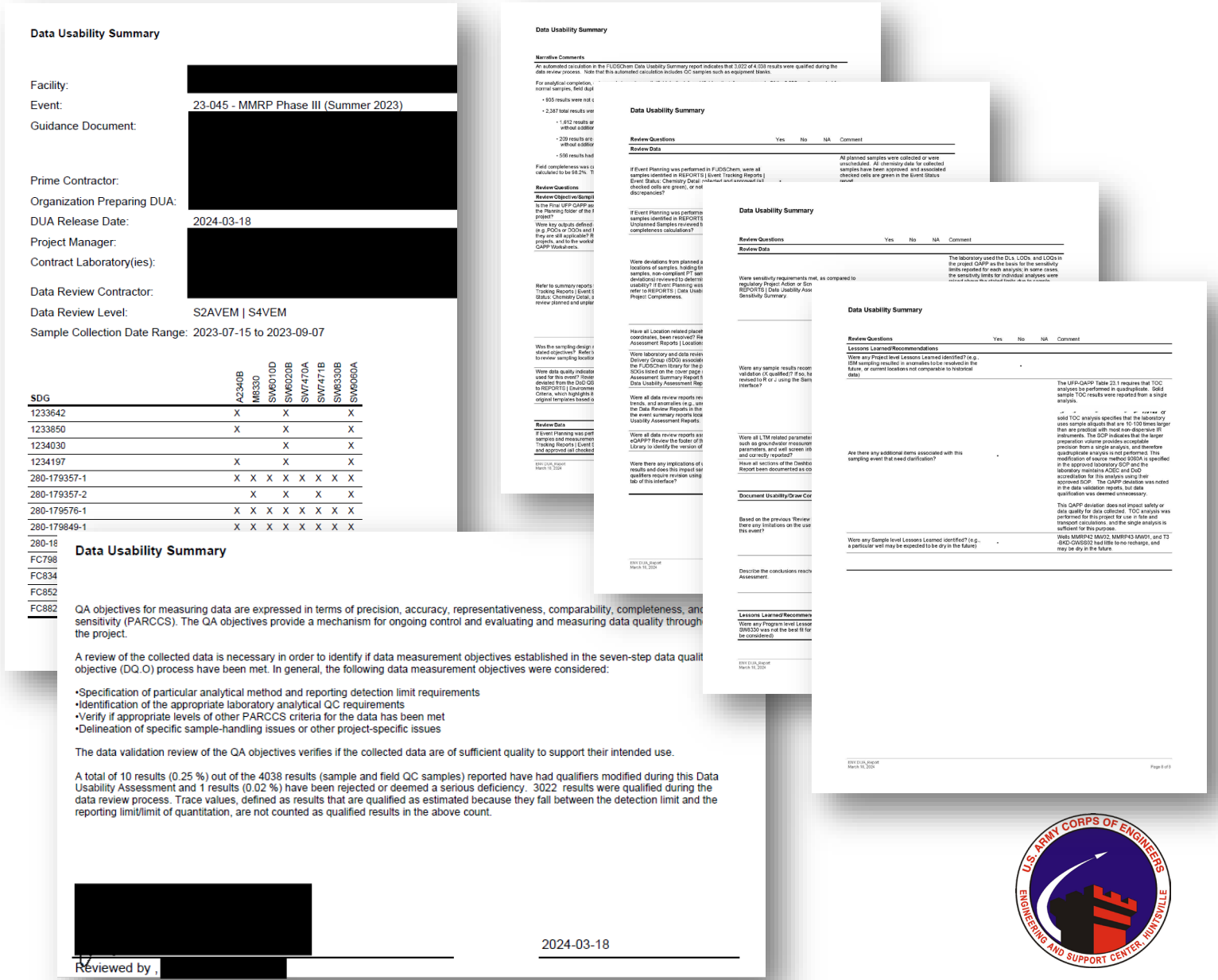
- Includes high-level summary of sampling event
- Narrative comments about overall quality of data set

Checklist

- Includes pre-determined questions which walk through the 5 steps of DUA
- Include sections for further discussion if needed
- Incorporates references to data discussions or data tables

Data Tables (not shown)

- Include all data and all final, approved qualifiers
- Indicates where qualifiers have been changed following Validation



Data Usability Summary

Facility: [redacted]
Event: 23-045 - MMRP Phase III (Summer 2023)
Guidance Document: [redacted]
Prime Contractor:
Organization Preparing DUA:
DUA Release Date: 2024-03-18
Project Manager:
Contract Laboratory(ies): [redacted]
Data Review Contractor:
Data Review Level: S2AVEM | S4VEM
Sample Collection Date Range: 2023-07-15 to 2023-09-07

SDG	A2340B	M8330	SW6010D	SW6020B	SW7470A	SW7471B	SW8330B	SW9060A
1233642	X			X				X
1233850	X			X				X
1234030				X				X
1234197	X			X				X
280-179357-1	X	X	X	X	X	X	X	X
280-179357-2		X		X		X		X
280-179576-1	X	X	X	X	X	X	X	X
280-179849-1	X	X	X	X	X	X	X	X
280-18								
FC798								
FC834								
FC852								
FC882								

Data Usability Summary

QA objectives for measuring data are expressed in terms of precision, accuracy, representativeness, comparability, completeness, and sensitivity (PARCCS). The QA objectives provide a mechanism for ongoing control and evaluating and measuring data quality through the project.

A review of the collected data is necessary in order to identify if data measurement objectives established in the seven-step data quality objective (DQ.O) process have been met. In general, the following data measurement objectives were considered:

- Specification of particular analytical method and reporting detection limit requirements
- Identification of the appropriate laboratory analytical QC requirements
- Verify if appropriate levels of other PARCCS criteria for the data has been met
- Delineation of specific sample-handling issues or other project-specific issues

The data validation review of the QA objectives verifies if the collected data are of sufficient quality to support their intended use.

A total of 10 results (0.25 %) out of the 4038 results (sample and field QC samples) reported have had qualifiers modified during this Data Usability Assessment and 1 results (0.02 %) have been rejected or deemed a serious deficiency. 3022 results were qualified during the data review process. Trace values, defined as results that are qualified as estimated because they fall between the detection limit and the reporting limit/limit of quantitation, are not counted as qualified results in the above count.

[redacted]

Reviewed by , [redacted]

2024-03-18

Data Usability Summary

Narrative Comments

Data Usability Summary

Review Questions | Yes | No | NA | Comment

Review Data

Data Usability Summary

Review Questions | Yes | No | NA | Comment

Review Data

Data Usability Summary

Review Questions | Yes | No | NA | Comment

Lessons Learned/Recommendations

THANK YOU

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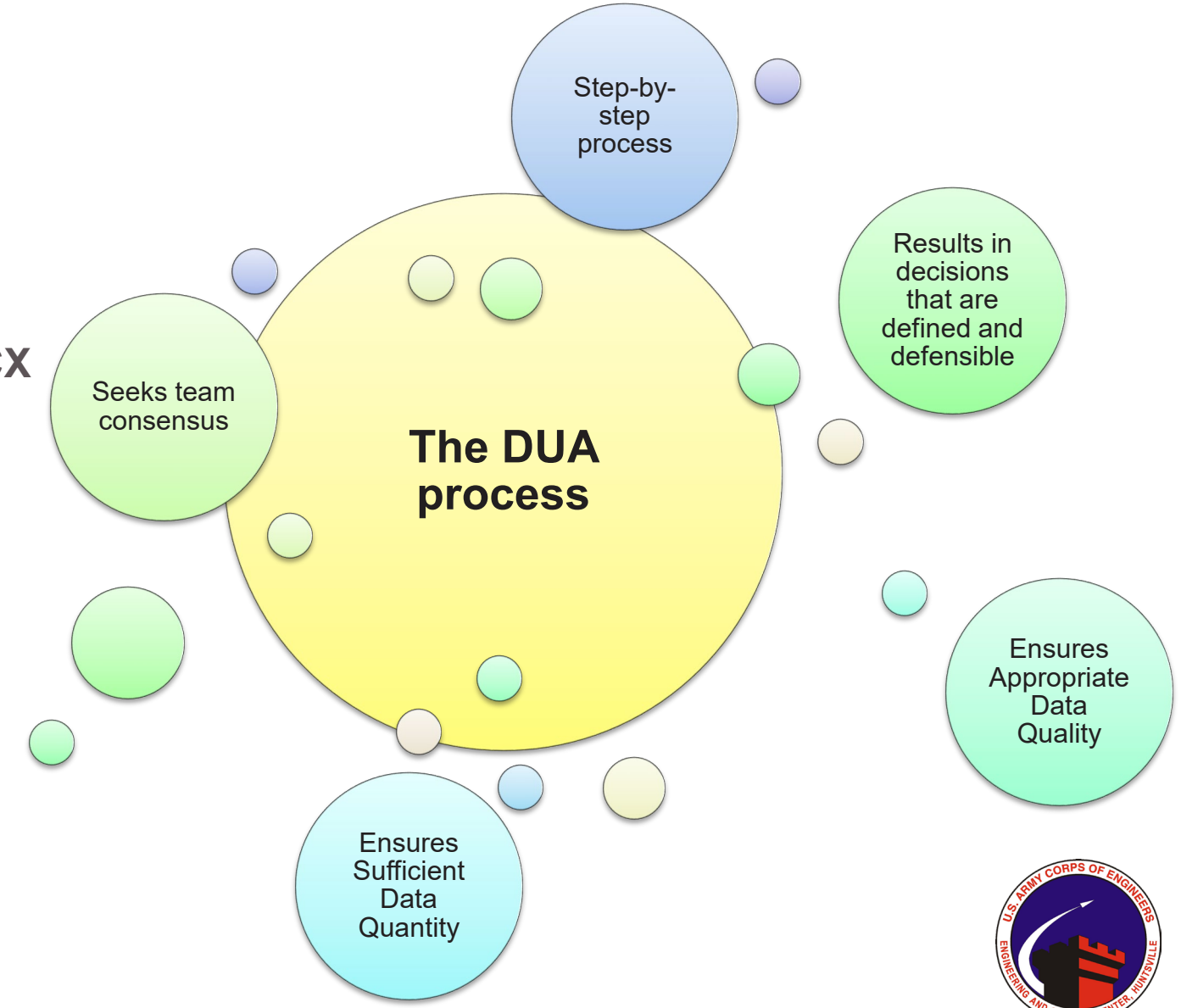
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