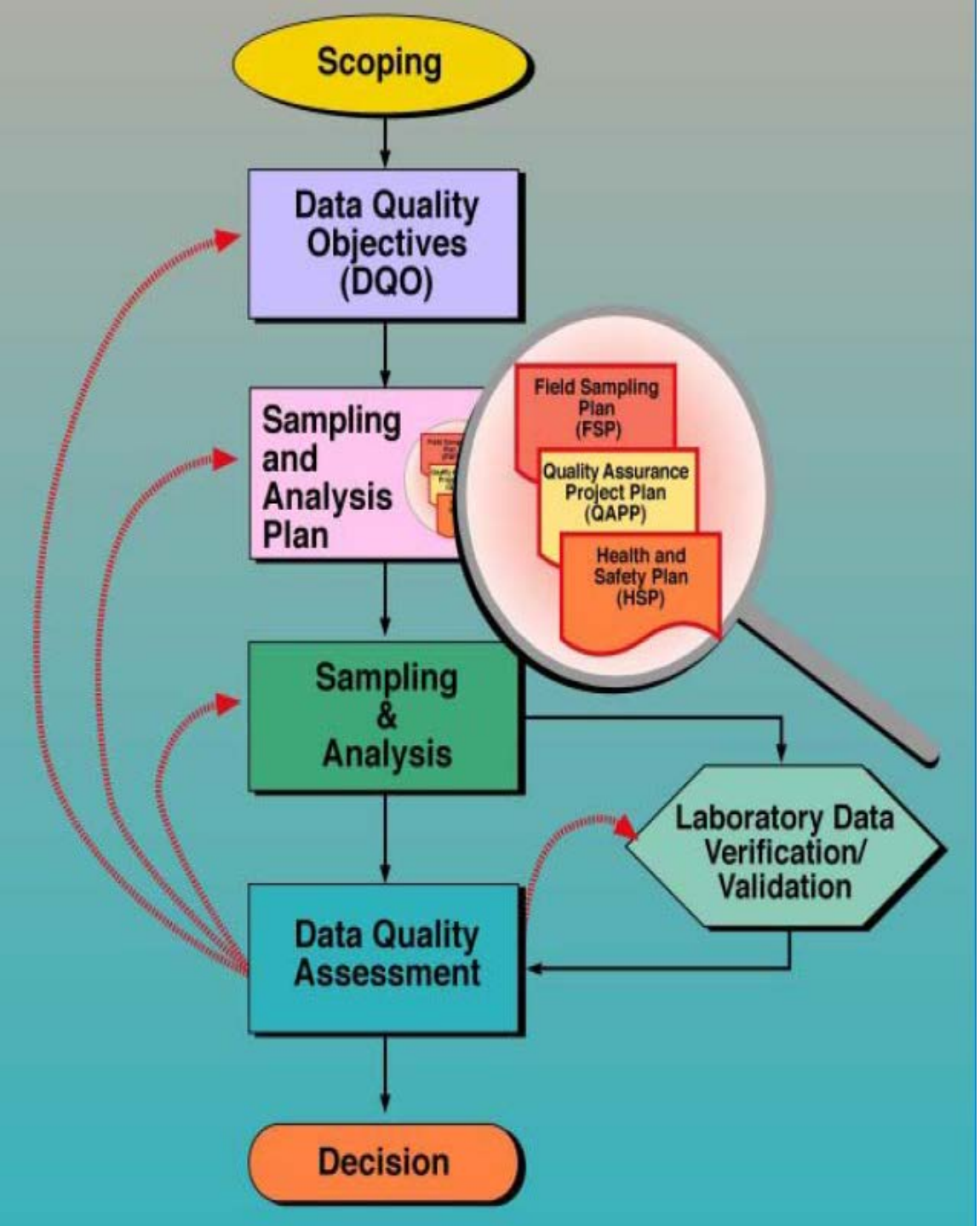
Quality Systems

ELTAC Meeting July 27, 2016

Quality System

- USEPA
  - The EPA Quality System encompasses management and technical activities related to the planning, implementation, assessment and improvement of environmental programs that involve:
  - the collection, evaluation and use of environmental data
  - the design, construction and operation of environmental technology
- It is about providing Regulators with Data of Sufficient Quality to make Public Health Decisions



1) The Starting Point of a Quality System Is the DQOs

2) The Axis on which a Quality System Turns is the DQA

3) Laboratory work is only one Part of the Quality System, Not Even the Majority

The Data Quality Objectives Process

- The EPA's DQO process provides a procedure for defining the criteria that a data collection design should satisfy.
- DQOs are used as the basis for establishing the quality and quantity of data needed to support a decision.
- What question do we want to answer?
- Use of a systematic planning process

Project Goal

- To determine whether methyl-mercury concentrations in catfish and bass tissue exceed the numeric tissue objective of 0.23 mg/kg in selected sites
- To determine whether methyl-mercury concentrations in water exceed the numeric objective of 0.14 ng/L in selected sites

Data Quality Objectives

Sufficient Levels of Accuracy and Precision to Determine if Regulatory Action Levels (e.g. TMDL) have been exceeded

Data Quality Indicators

- DQIs help objectively define the analytical capabilities and systems needed to address each DQO.

- For example, the DQI comparability would be emphasized by large programs/projects with many contributors. The DQI accuracy would be emphasized when DQOs reference regulatory action limits.

Data Quality Indicators

DQI	Assessment Method
Precision	Laboratory Duplicate, Matrix Spike Duplicate, Field Duplicate
Accuracy	Reference Materials, Matrix Spike, Matrix Spike Duplicate, Continuing Calibration Verification Standards
Representativeness	Data Quality Assessment
Comparability	PTs/Intercomparisons
Completeness	Data Verification
Sensitivity	MDL Studies, Calibration

Example Measurement Quality Objectives – MMHg

QC Sample	Frequency	Control Limits
Equipment Blanks Bottle Blanks	Random statistical testing	< MDL (0.020 ng/L) for low level samples < 1/5 sample concentration for high level samples
Field Blanks	1 per field event	< MDL (0.020 ng/L)
Field Duplicates	1 per 20 samples collected	RPD < 25%
Calibration Curve	1 per analytical day, consisting of 5 non-zero calibration points and 3 bubbler blanks	r > 0.995
Continuing Calibration Verification Standards (CCVs)	After initial calibration and after every 10 samples	80-120% recovery
Method Blanks	3 blanks per set of 20 field samples	Mean < ML (0.5 ng/L)
Reference Materials	1 per set of 20 field samples	70-130% recovery
Laboratory Duplicate	1 per set of 20 field samples	RPD < 25%
Matrix Spike	1 per set of 20 field samples	70-130% recovery
Matrix Spike Duplicate	1 per set of 20 field samples	70-130% recovery RPD < 25%

Data Quality Assessment

- Data Review, Verification, and Validation
- Verification and Validation Methods
- Reconciliation with User Requirements

Quality System

The Majority of a Quality System for Environmental Regulatory Compliance is Outside the purvey of Laboratories in General and ELAP in Particular

Quality System

1) California Regulators use Quality Systems right now
2) ELAP is not needed to Create and Use Quality Systems
3) How would ELAP Require Quality Systems?
4) How would it work with different Data Users having Different DQOs, DQIs, & MQOs?