PROJECT PLANNING PROCESS

Module 2

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EMS

Planning Questions

- What will we measure?
- Where?
- How?
- How much data do we need?

How will we know when to stop collecting data and make a decision?

No Planning

- We will measure everything everywhere with the highest possible precision and accuracy

- ***We will stop when the money runs out***

Directed Planning Process

- Involves all stakeholders, decisionmakers, and technical experts
- Involves technical experts as principals
- Each participant plays a constructive role in clearly defining:
  - The problem
  - Data the decisionmaker needs to resolve that problem
  - Why the decisionmaker needs that type and quality of data
  - The tolerable decision error rates
  - How the decisionmaker will use the data to make a defensible decision
- Encourage efficient planning by framing and organizing complex issues
- Promotes communication among the stakeholders
- ***Documentation*** provides project management with a more efficient and consistent transfer of knowledge to new project members

What Is A QA Project Plan?

- **Project Planning Documents are an important part of the Quality System**
- **Description of how data will be collected, assessed, and analyzed**
- **Project Blueprint: who, what, where, when, why**
  - how a particular project will achieve data of the type and quality needed and expected by the project planning team
- **Living document that is revised to reflect significant changes**
  - used and updated over the life of the project
- **QAPPs must be approved *prior to the start of sample collection and data analysis***

What Does A QA Project Plan Do For You?

When you are asked:

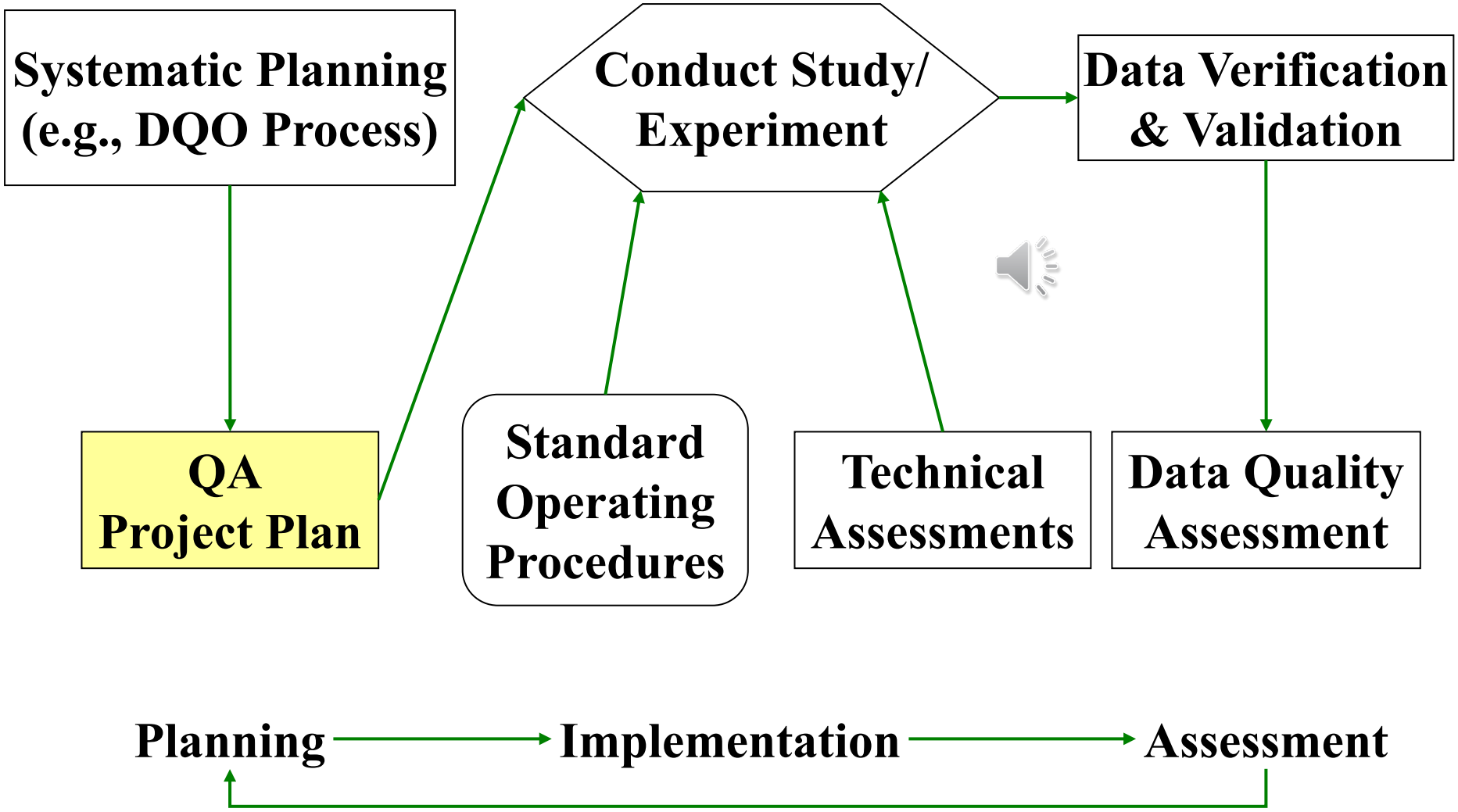
- **"What did you do?"**
- **"How did you do it?"**
- **"Why did you do it?"**
- **"Did you do it correctly?"**

The QA Project Plan has the answer.

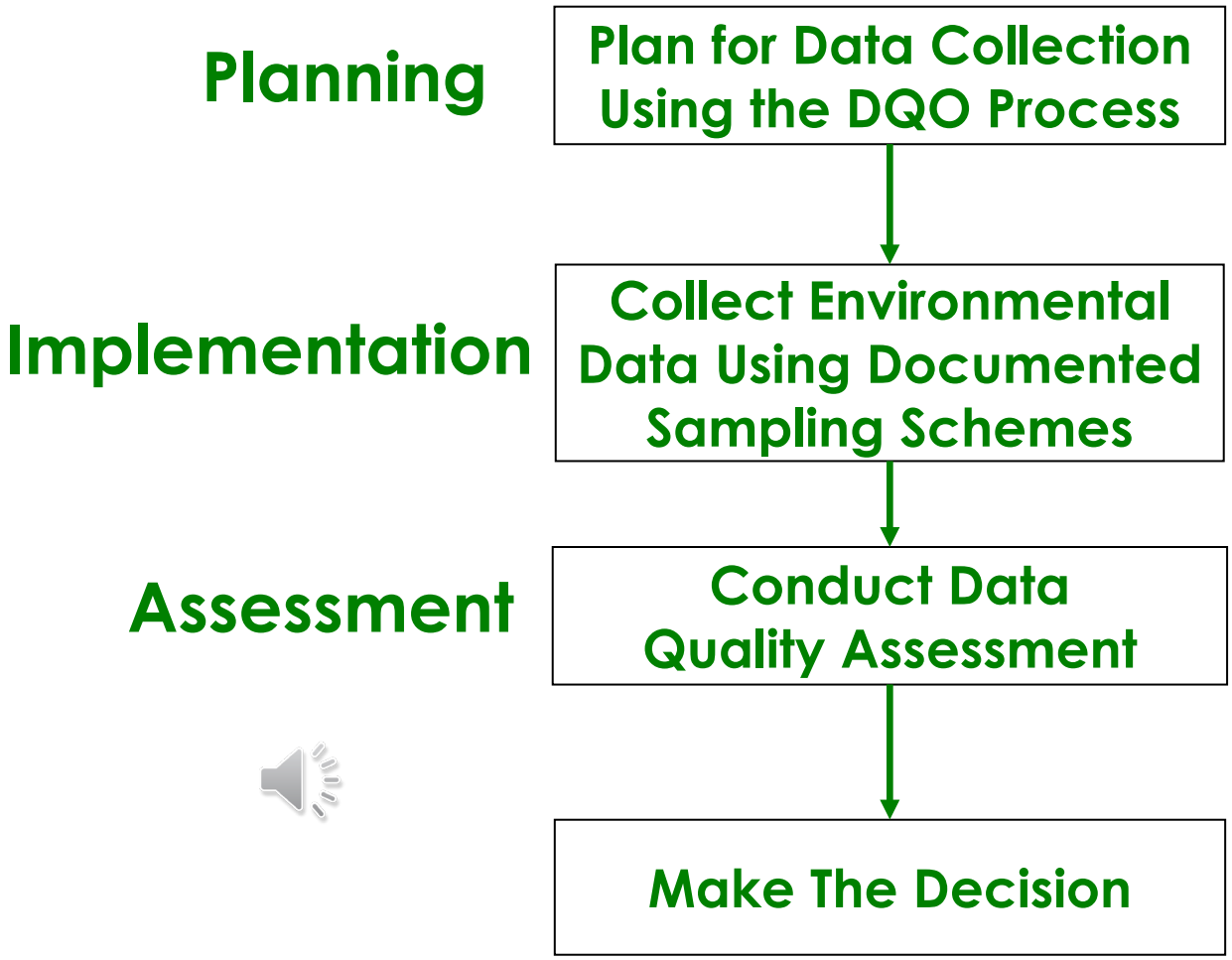
Elements of a QA Project Plan

Group A. Project Management Group	Group B. Data Generation and Acquisition	Group C. Assessment and Oversight
A1 Title and Approval Sheet	***B1 Sampling Process Design (Experimental Design)***	C1 Assessments and Response Actions
A2 Table of Contents	***B2 Sampling Methods***	C2 Reports to Management
A3 Distribution List	***B3 Sample Handling and Custody***	
A4 Project/Task Organization	***B4 Analytical Methods***	**Group D. Data Validation and Usability**
A5 Problem Definition and Background	***B5 Quality Control***	***D1 Data Review, Verification, and Validation***
A6 Project/Task Description	***B6 Instrument/Equipment Testing, Inspection, and Maintenance***	***D2 Verification and Validation Methods***
A7 Quality Objectives and Criteria	***B7 Instrument/Equipment Calibration and Frequency***	***D3 Reconciliation with User Requirements***
A8 Special Training/ Certifications	***B8 Inspection/Acceptance of Supplies and Consumables***	
A9 Documentation and Records	***B9 Non-direct Measurements***	
	B10 Data Management	

Link Between Project Planning and Project Plan Documents



DQOs in the Context of the Project Life Cycle



EPA QA/G-4
Guidance on Systematic Planning Using the Data Quality Objectives Process

EPA QA/G-5
Guidance for Quality Assurance Project Plans

EPA QA/G-9
Data Quality Assessment: Statistical Methods for Practitioners
EPA QA/G-9S

Data Quality Assessment: A Reviewer's Guide
EPA QA/G-9R

http://www.epa.gov/quality/qa_docs.html

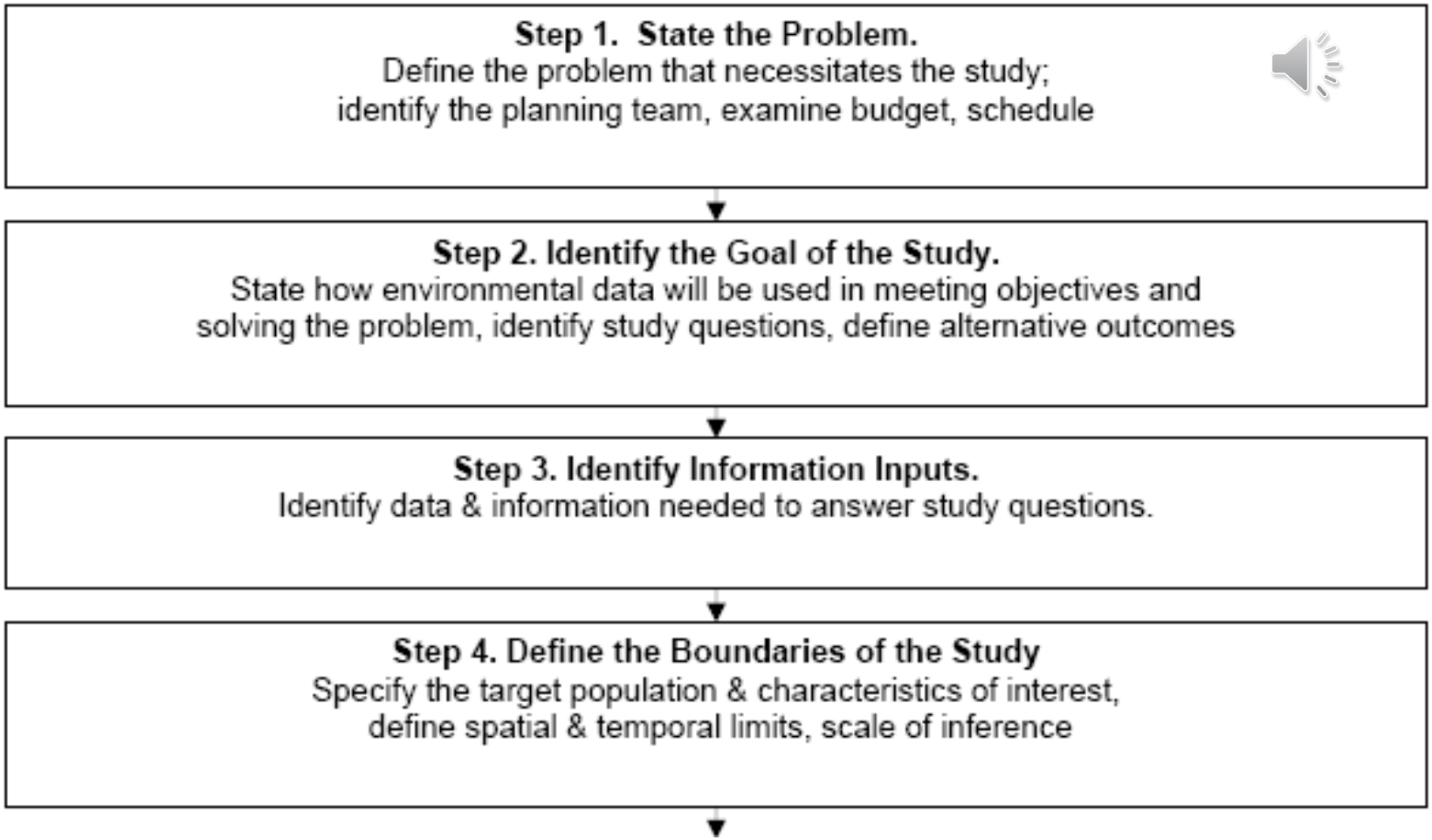
MARLAP Recommends…

- Use a **graded approach**
- Develop a **primary integrating project plan**
- Develop project plan documents - integrate all technical and quality aspects for the **life-cycle** of the project
- Include a report on the **directed planning process** in the project plan documents (by citation or in an appendix)
- Include a summary of the planning process if the planning process was not documented in a report
- Cite all assumptions and decisions, action levels, DQO statement, and APSs
- Use a formal process to control and document changes

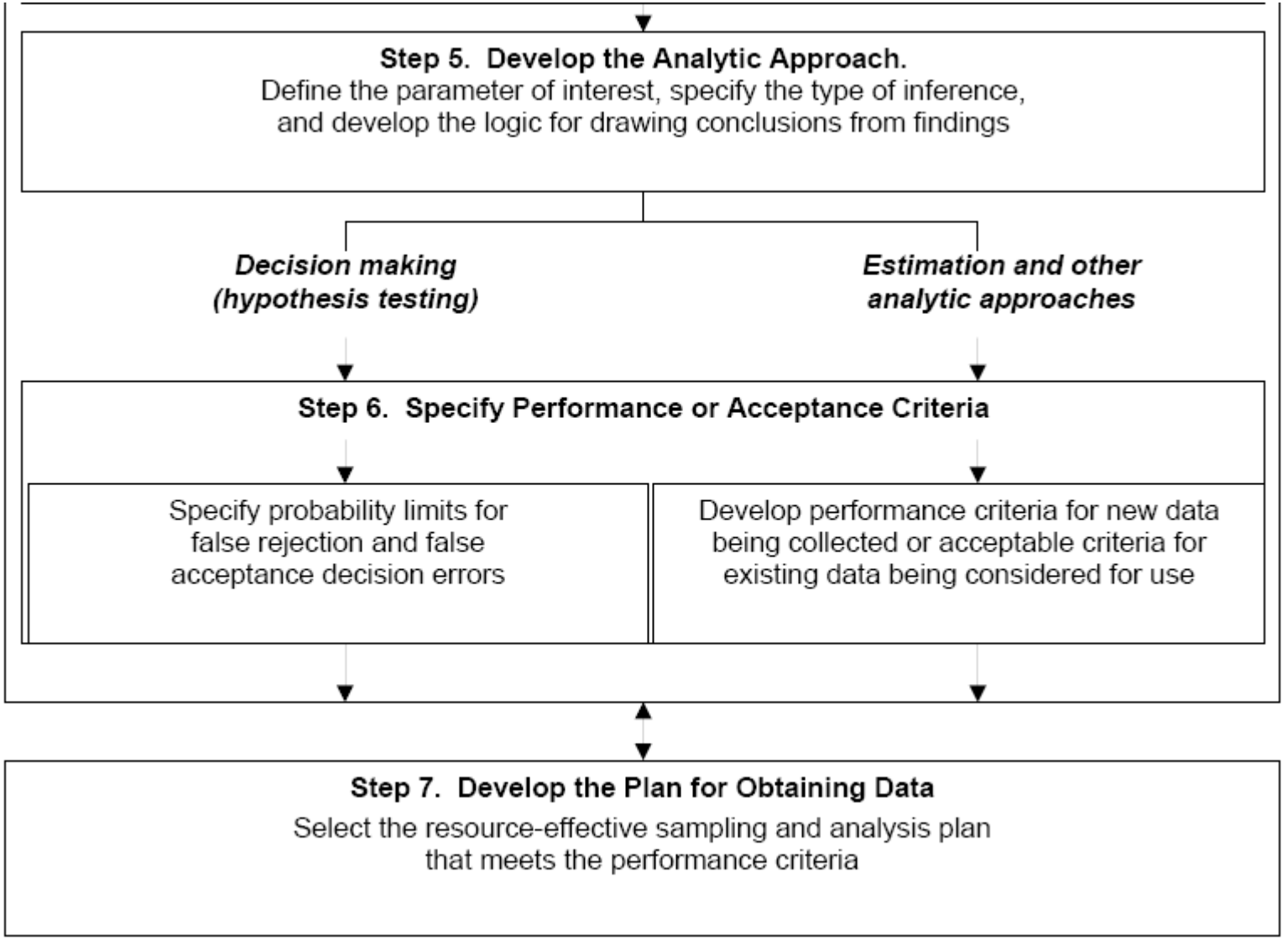
Directed Planning Process

1. State the problem
2. Identify the decision
3. Specify the decision rule and the tolerable decision error rates
4. Optimize the strategy for obtaining data

DQO Process Steps 1-4



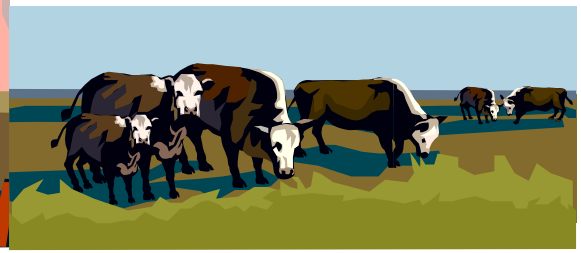
DQO Process Steps 5-7



Example Scenario

Does the milk from downwind cows have higher ^{90}Sr concentrations than that from upwind cows?

Downwind of Source



Potential Source of ^{90}Sr

Upwind of Source

1. State the Problem
(Section 2.5.1)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• Facts relevant to current situation (e.g., site history, ongoing studies). • Analytes of concern or analytes driving risk. • Matrix of concern. • Regulatory requirements and related issues. • Existing data and its reliability. • Known sampling constraints. • Resources and relevant deadlines.	• Evaluate existing radiological data for use in defining the issues (e.g., analytes of concern). • Assure that the perceived problem is really a concern by reviewing the underlying data that are the basis for the problem definition. • Consider how resource limitations and deadlines will impact measurement choices. • Use existing data to begin to define the analyte of concern and the potential range of concentrations.	• Problem defined with **specificity**. • Identification of the primary **decision-maker**, the available resources, and constraints.

From MARLAP Table 2.1

What is the question that needs an answer?

2a. Identify the Decision(s)
(Section 2.5.2)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• Analytical aspects related to the decision. • Possible **alternative actions**. • Sequence and priority for addressing the problem.	• Available protocols for sampling and analysis. • Provide focus on what analytes need to be measured, considering analyte relationships and background. • Begin to address the feasibility of different analytical protocols. • Begin to identify the items of the APSs. • Begin to determine how sample collection and handling will affect MQOs.	• Statements that **link the defined problem to the associated decisions and alternative actions.** 

What will be done based on the answer?

From MARLAP Table 2.1

2b. Identify Inputs to the Decisions
(Section 2.5.2.2)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• All useful **existing data**. • The general **basis** for establishing an action level. • Acquisition strategy **options** (if new data are needed).	• Review the quality and sufficiency of the existing radiological data. • Identify alternate analytes.	• Defined list of needed new data. • Define the characteristic or parameter of interest (analyte/matrix). • **Define the action level**. • Identify estimated concentration range for analytes of interest.

What criteria will determine the action taken ?

From MARLAP Table 2.1

2c. Define the Decision Boundaries (Section 2.5.2.3)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• Sampling or measurement **timeframe**. • Sampling areas and **boundaries**. • **Subpopulations**. • Practical constraints on data collection (season, equipment, turnaround time, etc.). • Available protocols.	• Identify temporal trends and spatial heterogeneity using existing data. • With the sampling specialists, identify practical constraints that impact sampling and analysis. • Determine feasibility of obtaining new data with current methodology. • Identify limitations of available protocols.	• Temporal and spatial boundaries. • The scale of decision.

What will the data taken actually represent?

From MARLAP Table 2.1

3a. Develop a Decision Rule (Section 2.5.3)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• Statistical parameter to describe the **parameter of interest** and to be compared to the action level. • The **action level** (quantitative). • The scale of decisionmaking.	• Available protocols for sampling and analysis. • Identify potentially useful methods. • Estimate measurement uncertainty and detection limits of available analytical protocols.	• **A logical, sequential series of steps ("if...then") to resolve the problem**.

What is the action level?

From MARLAP Table 2.1

Decision Rules

Data are collected so that decisions can be made about …

- … individual samples…*as for bioassays*
- … the mean of a sampled population … *as for MARSSIM final status surveys*

A decision rule has three parts:

- Parameter of Interest in a particular matrix
- Action Level
- Alternative Actions

Examples

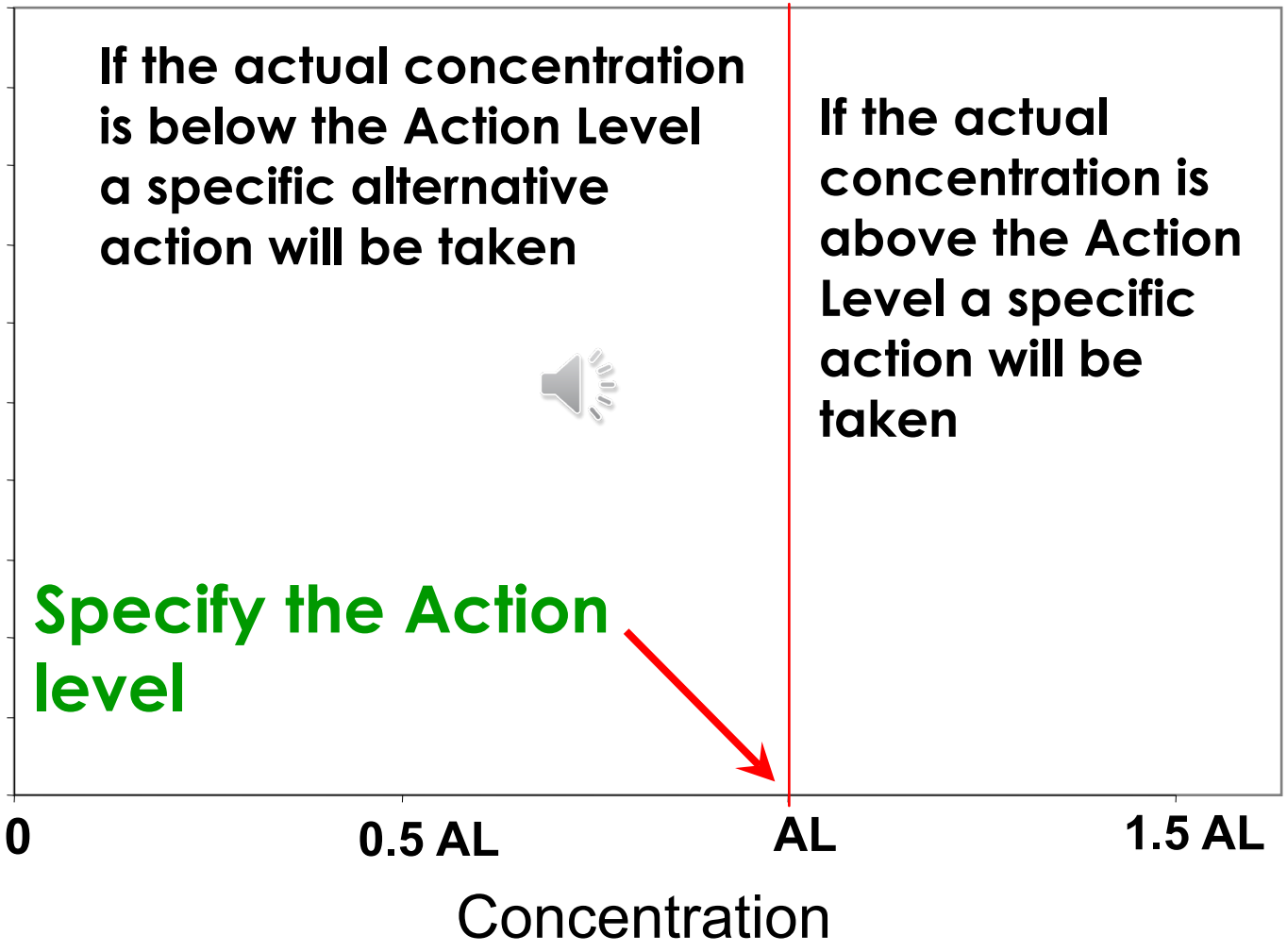
- *If the activity of a sample exceeds a certain level, conclude the sample contains the radionuclide(s) of interest and some action must be taken; otherwise conclude it does not.*

- *If the mean concentration in an area is less than the action level, conclude the area meets release criteria; otherwise conclude that corrective action must be taken.*

Decision Rules

The decisionmaker and planning team must be completely comfortable with the decision rule regarding the criteria for taking action

Action Level and Alternative Actions



DQOs and Uncertainty

*If there were **no** measurement uncertainty and **no** spatial variability, how many measurements would be needed to find the average concentration of a radionuclide in an area?*

How difficult would it be to apply the Decision Rule?

3b. Specify Limits on Decision Error Rates (Section 2.5.3)

Information Needed by the Project Planning Team	Radioanalytical Specialists Participation / Input	Output / Product
• Potential **consequences** of making wrong decisions. • Possible **range** of the parameter of interest. • Allowable **differences** between the action level and the actual value. • Tolerable level of decision errors or confidence.	• Assess variability in existing data for decisions on hypothesis testing or statistical decision theory. • Evaluate whether the tolerable decision error rates can be met with available laboratory protocols, or if the error tolerance needs to be relaxed or new methods developed.	• Defined baseline condition (null hypothesis) and quantitative estimates of acceptable decision error rates. • Defined range of possible parameter values where the consequence of a Type II decision error is relatively minor (gray region).

How far from the action level will significant consequences occur if the wrong action is taken?

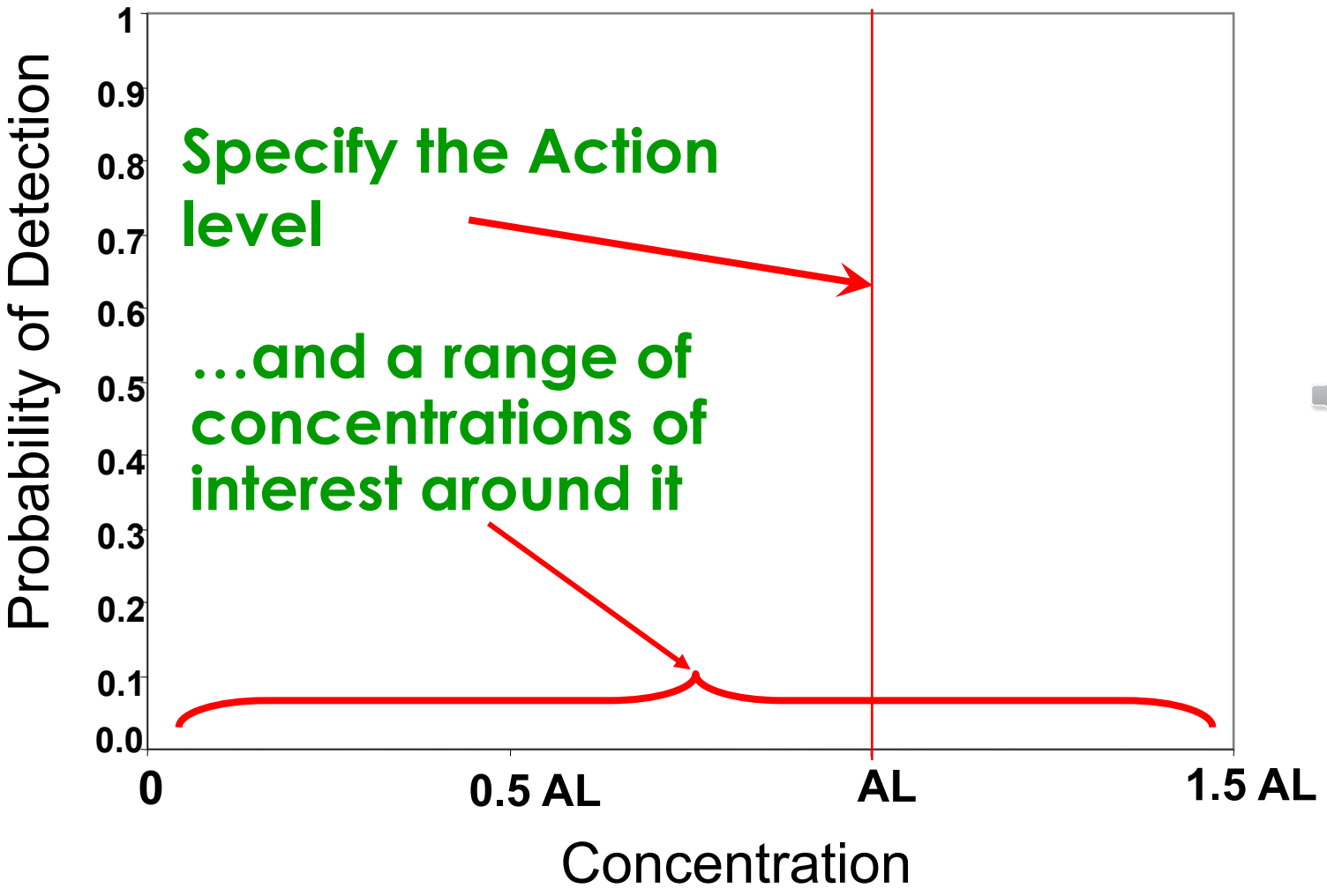
From MARLAP Table 2.1

DQOs and Uncertainty

No measurement program or sampling plan can be adequately designed without some estimate of the uncertainty in the data relative to the action level.

Total uncertainty = measurement uncertainty + spatial variability

Action Level and Range of Concentrations



Decision Rules

The decision rule will be applied by:

- Collecting data
- Computing test statistic related to the parameter of interest
- Conducting a statistical hypothesis test

Examples

- *If the counts from a sample exceed a certain level, conclude the sample truly contains the radionuclide(s) of interest; otherwise conclude it does not*

- *If the mean concentration from a set of samples is less than the action level, conclude the true concentration in the area from which the samples were taken meets release criteria; otherwise conclude that corrective action must be taken*

Statistical Hypothesis Tests

- Statistical hypothesis-testing provides a mechanism for deciding between two mutually exclusive statements based on the value of a test statistic calculated from the data.
- These statements are called the null hypothesis, $\mathbf{H_0}$, and the alternative hypothesis, $\mathbf{H_1}$.
- The null hypothesis is assumed to be true unless the value of the test statistic obtained is very improbable under that assumption. In that case the data are deemed inconsistent with the null hypothesis. Therefore, it is rejected and the alternative hypothesis is chosen instead.

Possible Decision Errors

DECISION	TRUE STATE	CONSEQUENCES
Reject H_0 …	… when it is actually true	Type I error (probability α)
Deciding not to reject H_0 …	**… when it is actually false**	Type II error (probability β)

4. Optimize the Strategy for Obtaining Data (Section 2.5.4)

- This section of MARLAP lists in tabular form the information needed by the project team to properly strategize for obtaining how many samples and what concentrations are needed.
- This coupled with the tolerable error rates and the range of concentrations expected provide a bases for determining the required method uncertainty.
- Radioanalytical Specialist!

From MARLAP Table 2.1

MARLAP Recommends…
(Section 2.8)

- Using a **directed project planning process**
- **Radioanalytical specialists** be a part of the integrated effort of the project planning team
- The planning **process rationale be documented** and the documentation integrated with the project plan documents
- A **graded approach** in which the sophistication, level of QC and oversight, and resources applied are appropriate to the project