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Standard Practice for Generation of Environmental Data Related to Waste Management Activities: Development of Data Quality Objectives[1]

This standard is issued under the fixed designation D5792; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers the process of development of data quality objectives (DQOs) for the acquisition of environmental data. Optimization of sampling and analysis design is a part of the DQO process. This practice describes the DQO process in detail. The various strategies for design optimization are too numerous to include in this practice. Many other documents outline alternatives for optimizing sampling and analysis design. Therefore, only an overview of design optimization is included. Some design aspects are included in the practice's examples for illustration purposes.

1.2 DQO development is the first of three parts of data generation activities. The other two aspects are (*1*) implementation of the sampling and analysis strategies, see Guide D6311 and (*2*) data quality assessment, see Guide D6233.

1.3 This guide should be used in concert with Practices D5283, D6250, and Guide D6044. Practice D5283 outlines the quality assurance (QA) processes specified during planning and used during implementation. Guide D6044 outlines a process by which a representative sample may be obtained from a population, identifies sources that can affect representativeness and describes the attributes of a representative sample. Practice D6250 describes how a decision point can be calculated.

1.4 Environmental data related to waste management activities include, but are not limited to, the results from the sampling and analyses of air, soil, water, biota, process or general waste samples, or any combinations thereof.

1.5 The DQO process is a planning process and should be completed prior to sampling and analysis activities.

1.6 This practice presents extensive requirements of management, designed to ensure high-quality environmental data. The words "must" and "shall" (requirements), "should" (recommendation), and "may" (optional), have been selected carefully to reflect the importance placed on many of the statements in this practice. The extent to which all requirements will be met remains a matter of technical judgment.

~~1.7The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.~~

1.7 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7.1 *Exception*—The values given in parentheses are for information only.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

C1215 Guide for Preparing and Interpreting Precision and Bias Statements in Test Method Standards Used in the Nuclear Industry

D5283 Practice for Generation of Environmental Data Related to Waste Management Activities: Quality Assurance and Quality Control Planning and Implementation

D5681 Terminology for Waste and Waste Management

D6044 Guide for Representative Sampling for Management of Waste and Contaminated Media

D6233 Guide for Data Assessment for Environmental Waste Management Activities

[1] This practice is under the jurisdiction of ASTM Committee D34 on Waste Management and is the direct responsibility of Subcommittee D34.01.01 on Planning for Sampling.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

D6250 Practice for Derivation of Decision Point and Confidence Limit for Statistical Testing of Mean Concentration in Waste Management Decisions

D6311 Guide for Generation of Environmental Data Related to Waste Management Activities: Selection and Optimization of Sampling Design

3. Terminology

~~3.1*Definitions:*~~

~~3.1.1~~

3.1 For definitions of terms used in this standard refer to Terminology D5681.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *bias*, *n*—the difference between the sample value of the test results and an accepted reference value.

~~3.1.1.1~~

3.2.1.1 *Discussion*—*Bias* represents a constant error as opposed to a *random error*. A method *bias* can be estimated by the difference (or relative difference) between a measured average and an accepted standard or reference value. The data from which the estimate is obtained should be statistically analyzed to establish *bias* in the presence of *random error*. A thorough *bias* investigation of a measurement procedure requires a statistically designed experiment to repeatedly measure, under essentially the same conditions, a set of standards or reference materials of known value that cover the range of application. *Bias* often varies with the range of application and should be reported accordingly. **C1215**

~~3.1.2~~

3.2.2 *confidence interval*, *n*—an interval used to bound the value of a population parameter with a specified degree of confidence (this is an interval that has different values for different samples).

~~3.1.2.1~~

3.2.2.1 *Discussion*—The specified degree of confidence is usually 90, 95, or 99 %. *Confidence intervals* may or may not be symmetric about the mean, depending on the underlying statistical distribution. For example, *confidence intervals* for the variances are not symmetric. **C1215**

~~3.1.3~~

3.2.3 *confidence level*, *n*—the probability, usually expressed as a percent, that a *confidence interval* is expected to contain the parameter of interest (see discussion of *confidence interval*).

~~3.1.4~~

3.2.4 *data quality objectives (DQOs)*, *n*—qualitative and quantitative statements derived from the DQO process describing the decision rules and the uncertainties of the decision(s) within the context of the problem(s).

~~3.1.4.1~~

3.2.4.1 *Discussion*—DQOs clarify the study objectives, define the most appropriate type of data to collect, determine the most appropriate conditions from which to collect the data, and establish acceptable levels of decision errors that will be used as the basis for establishing the quantity and quality of data needed to support the decision. The DQOs are used to develop a sampling and analysis design.

~~3.1.5~~

3.2.5 *data quality objectives process*, *n*~~—a quality management tool based on the scientific method and developed by the U.S. Environmental Protection Agency (EPA) to facilitate the planning of environmental data collection activities. The DQO process enables planners to focus their planning efforts by specifying the use of the data (the decision), decision criteria (decision point), and decision maker's acceptable decision error rates. The products of the DQO process are the DQOs.~~

~~3.1.5.1*Discussion*—DQOs result from an iterative process between the decision makers and the technical team to develop qualitative and quantitative statements that describe the problem and the certainty and uncertainty that decision makers are willing to accept in the results derived from the environmental data. This acceptable level of uncertainty should then be used as the basis for the design specifications for project data collection and data assessment. All of the information from the first six steps of the DQO process are used in designing the study and assessing the data adequacy. **EPA QA/G-4**~~

~~3.1.6~~—*Qualitative and Quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.*

3.2.6 *decision error*

~~3.1.6.1~~

3.2.6.1 *false negative error, n*—this occurs when environmental data mislead decision maker(s) into not taking action specified by a decision rule when action should be taken.

~~3.1.6.2~~

3.2.6.2 *false positive error, n*—this occurs when environmental data mislead decision maker(s) into taking action specified by a decision rule when action should not be taken.

~~3.1.7~~

3.2.7 *decision point*, *n*—the numerical value that causes the decision-maker to choose one of the alternative actions point (for example, compliance or noncompliance). **D6250**

~~3.1.7.1~~

3.2.7.1 *Discussion*—In the context of this practice, the numerical value is calculated in the planning stage and prior to the collection of the sample data, using a specified hypothesis, decision error, an estimated standard deviation, and number of samples. In environmental decisions, a concentration limit such as a regulatory limit usually serves as a standard for judging attainment of cleanup, remediation, or compliance objectives. Because of uncertainty in the sample data and other factors, actual cleanup or remediation, may have to go to a level lower or higher than this standard. This new level of concentration serves as a point for decision-making and is, therefore, termed the *decision point*.

~~3.1.8~~

3.2.8 *decision rule*, *n*—a set of directions in the form of a conditional statement that specify the following: (*1*) how the sample data will be compared to the decision point, (*2*) which decision will be made as a result of that comparison, and (*3*) what subsequent action will be taken based on the decisions.

~~3.1.9~~

3.2.9 *precision*, *n*—a generic concept used to describe the dispersion of a set of measured values.

~~3.1.9.1~~

3.2.9.1 *Discussion*—Measures frequently used to express *precision* are standard deviation, relative standard deviation, variance, repeatability, reproducibility, confidence interval, and range. In addition to specifying the measure and the *precision*, it is important that the number of repeated measurements upon which the estimated *precision* is based also be given.

~~3.1.10~~

3.2.10 *quality assurance (QA)*, *n*—an integrated system of management activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a process or service (for example, environmental data) meets defined standards of quality with a stated level of confidence. **EPA QA/G-4**

~~3.1.11~~

3.2.11 *quality control (QC)*, *n*—the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical. **EPA QA/G-4**

~~3.1.12~~

3.2.12 *population*, *n*—the totality of items or units of materials under consideration.

~~3.1.13~~

3.2.13 *random error*, *n*—(*1*) the chance variation encountered in all measurement work, characterized by the random occurrence of deviations from the mean value; (*2*) an error that affects each member of a set of data (measurements) in a different manner.

~~3.1.14~~

3.2.14 *risk*, *n*—the probability or an expected loss associated with an adverse effect.

~~3.1.14.1~~

3.2.14.1 *Discussion*—*Risk* is frequently used to describe the adverse effect on health or on economics. Health-based *risk* is the probability of induced diseases in persons exposed to physical, chemical, biological, or radiological insults over time. This *risk* probability depends on the concentration or level of the insult, which is expressed by a mathematical model describing the dose and *risk* relationship. *Risk* is also associated with economics when decision makers have to select one action from a set of available actions. Each action has a corresponding cost. The *risk* or expected loss is the cost multiplied by the probability of the outcome of a particular action. Decision makers should adopt a strategy to select actions that minimize the expected loss.

~~3.1.15~~

3.2.15 *sample standard deviation*, *n*—the square root of the sum of the squares of the individual deviations from the sample average divided by one less than the number of results involved.

$$S = \sqrt{\frac{\sum_{j=1}^{n} (X_j - \bar{X})^2}{n-1}}$$

where:
S = sample standard deviation,
n = number of results obtained,
X_j = jth individual result, and
$\bar{X}$ = sample average.

4. Summary of Practice

4.1 This practice describes the process of developing and documenting the DQO process and the resulting DQOs. This practice also outlines the overall environmental study process as shown in Fig. 1. It must be emphasized that any specific study scheme must be conducted in conformity with applicable agency and company guidance and procedures.

4.2 For example, the investigation of a Superfund site would include feasibility studies and community relation plans, which are not a part of this practice.

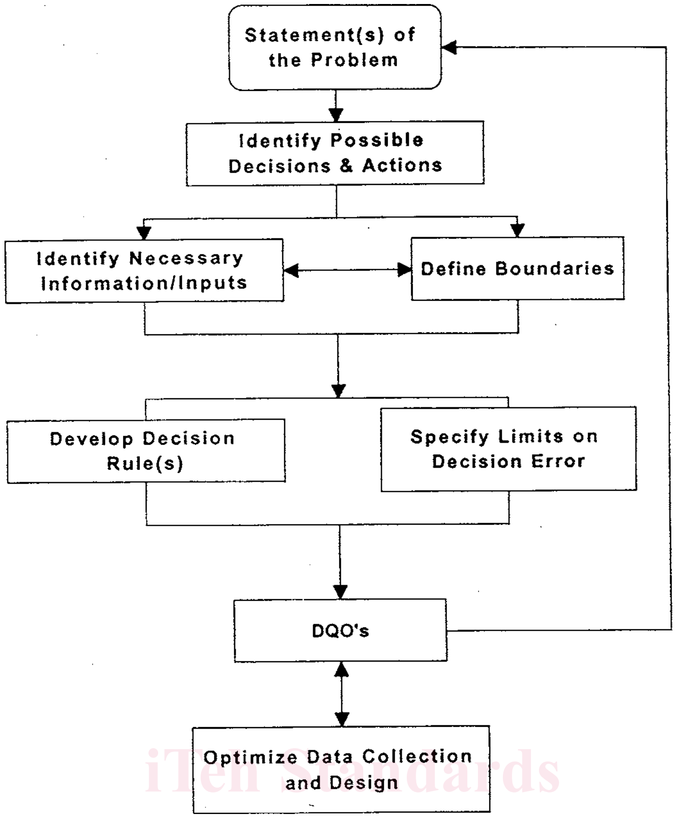

FIG. 1 DQO Process

5. Significance and Use

5.1 Environmental data are often required for making regulatory and programmatic decisions. Decision makers must determine whether the levels of assurance associated with the data are sufficient in quality for their intended use.

5.2 Data generation efforts involve three parts: development of DQOs and subsequent project plan(s) to meet the DQOs, implementation and oversight of the project plan(s), and assessment of the data quality to determine whether the DQOs were met.

5.3 To determine the level of assurance necessary to support the decision, an iterative process must be used by decision makers, data collectors, and users. This practice emphasizes the iterative nature of the process of DQO development. Objectives may need to be reevaluated and modified as information related to the level of data quality is gained. This means that DQOs are the product of the DQO process and are subject to change as data are gathered and assessed.

5.4 This practice defines the process of developing DQOs. Each step of the planning process is described.

5.5 This practice emphasizes the importance of communication among those involved in developing DQOs, those planning and implementing the sampling and analysis aspects of environmental data generation activities, and those assessing data quality.

5.6 The impacts of a successful DQO process on the project are as follows: (*1*) a consensus on the nature of the problem and the desired decision shared by all the decision makers, (*2*) data quality consistent with its intended use, (*3*) a more resource-efficient sampling and analysis design, (*4*) a planned approach to data collection and evaluation, (*5*) quantitative criteria for knowing when to stop sampling, and (*6*) known measure of risk for making an incorrect decision.

6. Data Quality Objective Process

6.1 The DQO process is a logical sequence of seven steps that leads to decisions with a known level of uncertainty (Fig. 1). It is a planning tool used to determine the type, quantity, and adequacy of data needed to support a decision. It allows the users to collect proper, sufficient, and appropriate information for the intended decision. The output from each step of the process is stated in clear and simple terms and agreed upon by all affected parties. The seven steps are as follows:

(1) Stating the problem,
(2) Identifying possible decisions,
(3) Identifying inputs to decisions,
(4) Defining boundaries,
(5) Developing decision rules,
(6) Specifying limits on decision errors, and
(7) Optimizing data collection design.

All outputs from steps one through six are assembled into an integrated package that describes the project objectives (the problem and desired decision rules). These objectives summarize the outputs from the first five steps and end with a statement of a decision rule with specified levels of the decision errors (from the sixth step). In the last step of the process, various approaches to a sampling and analysis plan for the project are developed that allow the decision makers to select a plan that balances resource allocation considerations (personnel, time, and capital) with the project's technical objectives. Taken together, the outputs from these seven steps comprise the DQO process. The relationship of the DQO process to the overall project process is shown in Fig. 2. At any stage of the project or during the field implementation phase, it may be appropriate to reiterate the DQO process, beginning with the first step based on new information. See Refs **(2, 3)** for examples of the DQO process.

6.2 *Step 1—Stating the Problem*:

6.2.1 *Purpose*—The purpose of this step is to state the problem clearly and concisely. The first indication that a problem (or issue) exists is often articulated poorly from a technical perspective. A single event or observation is usually cited to substantiate that a problem exists. The identity and roles of key decision makers and technical qualifications of the problem-solving team may not be provided with the first notice. Only after the appropriate information and problemsolving team are assembled can a clear statement of the problem be made.

6.2.2 *Activities*:

6.2.2.1 *Assembling of all Pertinent Information*—The necessary first action to describe a problem is to verify the conditions that indicate a problem exists. The pertinent information should be assembled during this phase of problem definition. A key source is any historical record of events at the site where the problem is believed to exist. This enables the decision makers to understand the context of the problem. A series of questions need to be developed concerning the problem.

(1) What happened (or could happen) that suggests a problem?
(2) When did it (could it) happen?
(3) How did it (could it) happen?
(4) Where did it (could it) happen?
(5) Why did it (could it) happen?
(6) How bad is (might be) the result or situation?
(7) How fast is (might be) the situation changing?
(8) What is (could be) the impact on human health and the environment?
(9) Who was (could be) involved?
(10) Who knows (should know) about the situation?
(11) Has anything been (might anything be) done to mitigate the problem?
(12) What contaminants are (could be) involved?
(13) How reliable is the information?

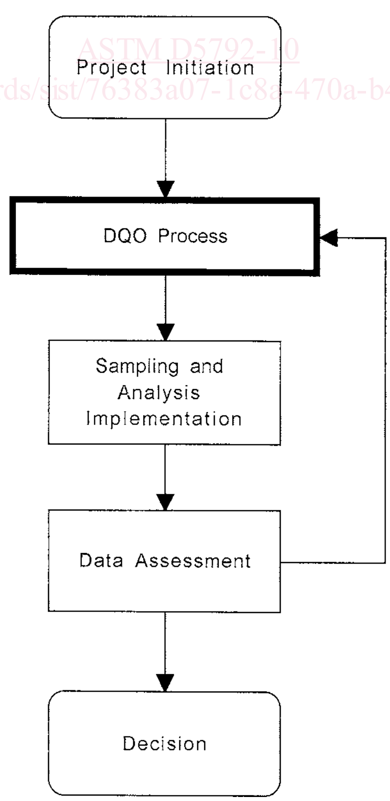

FIG. 2 DQOs Process and Overall Decision Process

(14) What regulations could or should apply?

(15) Is there any information that suggests there is not a problem?

This list of potential information is not exhaustive, and there may be other data applicable to the definition of the problem.

6.2.2.2 *Identification of the DQO Team*—Even as information is being gathered, it is necessary to begin assembling a team of decision makers and technical support personnel to organize and evaluate the information. These individuals become the core of the DQO team and may be augmented by others as information and events dictate. The decision makers who have either jurisdiction over the site and personnel or financial resources that will be used in resolving the problem usually determine the identities and roles of the DQO team members. The DQO team is usually made up of the following key individuals:

(1) Site Owners or Potentially Responsible Parties—These individuals have authority to commit personnel and financial resources to resolve the problem and have a vital interest in the definition of the problem and possible decisions.

(2) Representatives of Regulatory Agencies—These individuals are usually responsible for enforcing the standards that have been exceeded, leading to classifying the observations or events as a problem. Additionally, they have an active role in characterizing the extent of the problem, approving any proposed remedial action, and concurring that the action mitigated the problem.

(3) Project Manager—This individual generally has the responsibility for overseeing resolution of the problem. This person may represent either the regulatory agency or the potentially responsible parties.

(4) Technical Specialists—These individuals have the expertise to assess the information and data to determine the nature and extent of the potential problem and may become key players in the design and implementation of proposed decisions.

It is important that these individuals be assembled early in the process and remain actively involved to foster good communications and to achieve consensus among the DQO team on important decision-related issues.

6.2.3 *Outputs*:

6.2.3.1 *Statement of Problem and Context*—Once the initial information and data have been collected, organized, and evaluated, the conclusions of the DQO team should be documented. If it is determined that no problem exists, the conclusion must be supported by a summary of the existing conditions and the standards or regulatory conditions that apply to the problem.

(1) If a problem is found to exist, the reasons must be stated clearly and concisely. Any standards or regulatory conditions that apply to the situation must be cited. If the initial investigation concludes that the existing conditions are the result of a series of problems, the DQO team should attempt to define as many discrete problems (or issues) as possible.

(2) The following are examples of problem statements:

(*a*) A former pesticide formulation facility is for sale, but it is unknown whether it meets local environmental standards for property transfer.

(*b*) An industrial site is known to be contaminated with low levels of lead, but it is unknown whether levels are below risk-based standards.

(*c*) Most of a vacant lot is believed to be uncontaminated with PCBs (<2 ppm), but it is unknown whether abandoned, leaky transformers in the vacant lot make it necessary to remove any of the top layer of soil.

(*d*) The former industrial site has contaminated soil areas that may be contaminating ground water, and it is necessary to decide which type of monitoring program will satisfy local health requirements.

(*e*) The city would like to use local ground water on an athletic field near a Superfund site, but must know how this water will impact the health of the athletes and spectators.

(3) Complex problems should be broken down into manageable smaller problems that are linked together to form the final decision. As an example, the sale of a piece of property may involve solving the following problems:

(*a*) Is the site contaminated? If yes, then,

(*b*) Is off-site disposal required? If no, then

(*c*) Which of two allowable on-site treatment options should be used?

6.2.3.2 *Identification of Resources*—As the nature and magnitude of the problem is being documented, the decision makers should be conferring to determine the type and amount of resources that can be committed. Preliminary budget, personnel assignments, and schedule should be established. Preliminary milestones, timelines, and approvals should be documented and concurred upon by affected decision makers. The DQO team leader and technical specialists should be included in these discussions where possible. At a minimum, they should be kept informed of these issues so their impact can be anticipated in the definition of the problem.

(1) Fig. 3 shows the primary components of the problem statement step. After this step is completed, the DQO team moves on to the next step, where the process to resolve the problem continues.

(2) It is important to remember that the DQO process is an iterative one. New information is collected as projects proceed. The DQO team members associated with the problem-statement step should remain involved with the DQO process. If new data, unavailable to the DQO team during the development of the problem statement, demonstrates that the statement is incomplete or otherwise inadequate, the problem statement should be reconsidered.

6.3 *Step 2—Identifying Possible Decisions*:

6.3.1 *Purpose*—The purpose of this step is to identify the possible decision(s) that will address the problem. Multiple decisions are required when the problem is complex. Information required to make decisions and to define the domain or boundaries of the

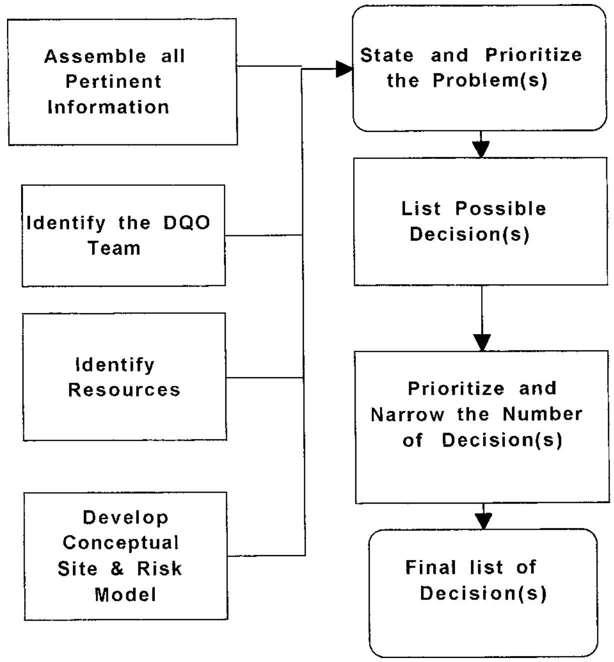

FIG. 3 Stating the Problem and Identifying the Decisions

decision will be determined in later steps (6.4 and 6.5, respectively). Each potential decision is tested to ensure that it is worth pursuing further in the process. A series of one or more decisions will result in actions that resolve the problem. The activities that lead to identifying the decision(s) are shown in Fig. 3 and discussed in 6.3.2.

6.3.2 *Activities*:

6.3.2.1 *Listing of Possible Questions Leading to Decisions*—All possible decisions concerning the problem should be listed. Choices should not be eliminated at this time. Possible decision statements are presented in the form of a series of questions that, when answered, result in actions that will resolve the problem. Examples of questions related to problems given in 6.2.3 (Step 1) are as follows:

(1) Are possible contaminants on the site below regulatory thresholds?

(2) Must all of the surface soil be remediated to less than 5 ppm lead?

(3) Can only locations with PCB levels above 2 ppm be remediated?

(4) Will a ground water monitoring program at the site capable of detecting contaminants at the 5-ppm level satisfy regulatory requirements?

(5) Will a single monitoring point on or near the athletic field be sufficient?

6.3.3 *Output*—After all possible decisions that might be made have been documented, those determined to be most appropriate to resolve the problem should be prioritized by the DQO team in decreasing order of level of effort (available resources and technical challenge). Justification for the rankings should be provided. The recommended sequence in which the decisions are made should also be listed. In cases in which a complex decision statement has been broken down into a series of simpler decisions, the DQO team should identify whether the individual decisions should be addressed sequentially or in parallel. After the possible decisions have been identified, the DQO team focuses on gathering the information necessary to formulate the decision statements in Step 3 (6.4).

6.4 *Step 3—Identifying Inputs to Decisions*:

6.4.1 *Purpose*—The answers to each of the questions identified by the previous step in the DQO process must be resolved with data. Fig. 4 shows the key activities that lead to development of the data requirements. This sequence of activities must be performed for each question. Note that the limits of the study (or boundary conditions) are determined in a parallel step identified as "define boundaries" in Fig. 1. This is another type of data requirement and is discussed in 6.4.

6.4.2 *Activities*:

6.4.2.1 *Determination of Data Requirements*—At this stage of the process, it is important to carefully examine the complete set of data requirements needed to support each of the decisions. Each possible decision to be made should be considered independently of others to ensure that no omissions have occurred. After all possible questions concerning the decisions have been considered, group the data requirements together to determine overall data needs for the project. It may be possible to plan efficiencies in collecting and processing data to meet multiple needs and thereby lower overall project costs or reduce the time necessary to meet important milestones, or both.

(*1*) When considering whether specific information is needed for making a decision, test the data to ensure that it is appropriate for the decision statement. If no use of the data can be identified, it may be extraneous to the needs.

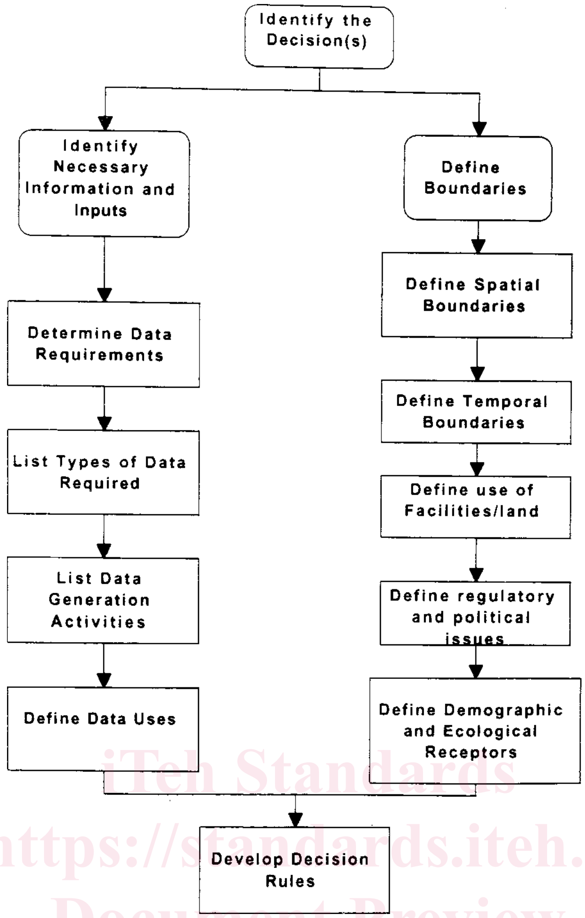

FIG. 4 Determination of Information Inputs and Study Boundaries

(2) The following list is indicative of some of the information needs that may be considered for each decision. It is not inclusive of all important data, but it provides examples common to many environmental problems.

(a) What regulatory limits may be associated with the problem or regulatory issue?
(b) Does contamination exceed regulatory limits?
(c) What tests must be performed for the type of waste in question?
(d) What are the hydrogeological considerations?
(e) What populations are at risk?
(f) What are the ecological considerations?
(g) What process knowledge is available?
(h) What historical/background data (past uses or spills) are available?
(i) What are the budget constraints?
(j) What is the time schedule?
(k) What potential health, political, and social factors must be considered?
(l) What is the potential for legal action?
(m) Who is the end-user of the data?
(n) What data validation criteria will be used?
(o) What, if any, limitations exist on the data collection process (detection limits, matrix interferences, or no known measurement technology)?

6.4.3 *Outputs*:

6.4.3.1 The DQO team must specify data needs for each problem/decision that has been identified in the first two steps.

6.4.3.2 List the types of data required. Some example data types include, but are not limited to, the following:

(1) Chemical,
(2) Physical (including site hydrogeology and meteorology),
(3) Biological,
(4) Toxicological,
(5) Historical,
(6) Economic (time, budget, and manpower),

(7) Demographic,

(8) Toxicity characteristics, and

(9) Fate and transport model output.

6.4.3.3 *Listing of Data Generation Activities*—Determine which data can be acquired from historical records and which new data must be obtained in the field or laboratory, or both. If the DQO team determines that no new data are necessary to make a decision, they should document their reasoning. If new information is necessary, activities that will be required to generate inputs (data) affecting the decision should be listed. Examples of these include, but are not limited to, the following:

(1) Assembly of historical data,

(2) Sampling and chemical analysis,

(3) Physical testing, and

(4) Modeling.

6.4.3.4 *Definition of Data Use(s)*—Each set of data will be used for some purpose. This purpose must be defined. For example, will regulatory thresholds for contaminants be determined by a risk-based calculation, by reference dose, or by pre-defined threshold values established by regulators? If so, ensure that data requirements are consistent with the criteria against which they will be compared. Data collected at the parts per million level may not be useful if they are to be compared to criteria at the parts per billion level.

6.5 *Step 4—Defining Boundaries*:

6.5.1 *Purpose*—This step of the DQO process determines the boundaries to which the decisions will apply. Boundaries establish limits on the data collection activities identified in Step 3 (6.4). These boundaries include, but are not limited to, spatial boundaries (physical and geographical), temporal boundaries (time periods), demographic, regulatory, political, and budget. The activities for this step of the DQO process are shown in Fig. 4.

6.5.2 *Activities*:

6.5.2.1 *Definition of Spatial Boundaries*—Define the boundaries of the total area and smallest increment of concern. Examples of items affecting the boundary definition are as follows:

(1) Horizontal or lateral areas,

(2) Vertical boundaries (depth/height),

(3) Discrete locations (hot spots),

(4) Media/matrix (air, soil, water, biota, and waste),

(5) Number of containers of waste, and

(6) Volume.

6.5.2.2 *Definition of Temporal Boundaries (Time Period)*—This activity determines the time interval over which environmental data will be collected for use in the decision-making process. If current or future real-time data are used to represent or model previous conditions, the basis of these assumptions or models must be documented and agreed upon between the decision makers and the technical team. The same constraint is also placed on the extrapolation of historical or real-time data, or both, to future time periods.

(*1*) The duration of new data collection activities must be established. In addition, the following factors should be considered:

(*a*) Availability and reliability of existing historical data,

(*b*) Access to the site or impacted area,

(*c*) Exposure potential, and

(*d*) Budgetary constraints.

6.5.2.3 *Definition of the Demographic Receptors*—The DQO team must frequently define the receptor population that may be effected. All affected populations and the mode of their anticipated exposure should be identified. These populations include the following:

(1) Known/Anticipated Population(s)—Human (children, adults, age, gender, and so forth), plant/animal (wetlands, endangered species, and so forth), and global;

(2) Population activity patterns; and

(3) Exposure pathway for each population.

6.5.2.4 *Definition of Nontechnical Boundaries*—Decision makers also have to consider nontechnical boundaries that can impact the resolution of the problem seriously. These nontechnical boundaries include the following:

(1) Regulatory considerations, and

(2) Political or legal action(s).

6.5.3 *Outputs*—The results from each of the activities in this step must be documented. Care must be taken to identify which boundary conditions apply to each decision being made. It may be that similar information is needed for several decisions but different boundary conditions may apply. It is important that decision makers understand and concur on the boundaries; otherwise, the ability to make decisions may be compromised.

6.6 *Step 5—Developing Decision Rules*:

6.6.1 *Purpose*:

6.6.1.1 The purpose of this step is to integrate outputs from previous steps into a set of statements that describe the logical basis for choosing among alternative outcomes/results/actions. These statements are decision rules that define the following:

(1) How the sample data will be compared to the regulatory threshold or to the decision point,

(2) Which decision(s) will be made as a result of that comparison, and

(3) What subsequent action(s) will be taken based on the decisions.

Greater details on how a decision rule is formulated can be found in Practice D6250.

6.6.1.2 The formats for these rules are either "if (criterion) ..., then (action)" statements or a decision tree, as shown in Fig. 5. The decision criteria should be stated as clearly and concisely as possible. The rule(s) must contain both a decision point (or decision point) and an action. The decision rule is generated through a cooperative effort among the DQO team. If an acceptable decision rule cannot be formulated, the process returns to the appropriate previous step of the DQO process.

6.6.1.3 Decision rules usually contain the following elements: measurement of interest, sample statistic, decision point, and a resultant action. "Measurement of interest" is the variable or attribute to be measured. It can be concentration of a contaminant, volume/mass of a waste, or physical property, such as flash point of a waste. "Sample statistic" is the quantity computed from the sample data. It can be average value, median, present/absent, or some other expression of quantity. If that data are not normally distributed, statistical methods based on other distributions or non-parametric methods can be used.

6.6.1.4 The "decision point" is the limit against which the sample statistic will be compared (see X1.2.7.5 for example). Depending on whether the decision point is exceeded or not, the specified action will result. If the decision point equals the regulatory threshold, the probability of a false positive error equals the probability of a false negative error. For unequal probabilities of the decision errors, the decision point can be either less or greater than the regulatory threshold. The degree to which the decision point is different from the regulatory threshold depends on the acceptable level of uncertainty for the decision errors that the decision makers are willing to accept. The levels of false positive error, false negative error, variability, and number of samples determine the decision point. Derivation of a decision point for a given level of false positive and false negative error is included as part of Appendix X1.

6.6.1.5 The decision rule is completed by stating the "resultant action" to be taken based on comparison of the sample statistic with the decision point.

6.6.1.6 An illustration of general decision rule formats are as follows:

(1) "If the average concentration of a contaminant in waste is greater than the decision point for that contaminant, then the waste will be classified as a 'hazardous' waste and will be disposed of according to the governing regulations."

(2) "If the average concentration of a contaminant in a waste is lower than the decision point for that contaminant, then the waste is classified as 'nonhazardous' and there are no special limitations placed on the disposal options.

6.6.1.7 In this illustration, the measurement of interest is "concentration of a contaminant." The sample statistic is the "average concentration." The decision point is some value to be specified. The resultant action is "disposal according to governing regulations." There may be separate decision rules for each medium, each domain (site), or other designated collections of data.

6.6.1.8 The decision point may be an observation or occurrence in some cases. An example of this type of decision rule is as follows:

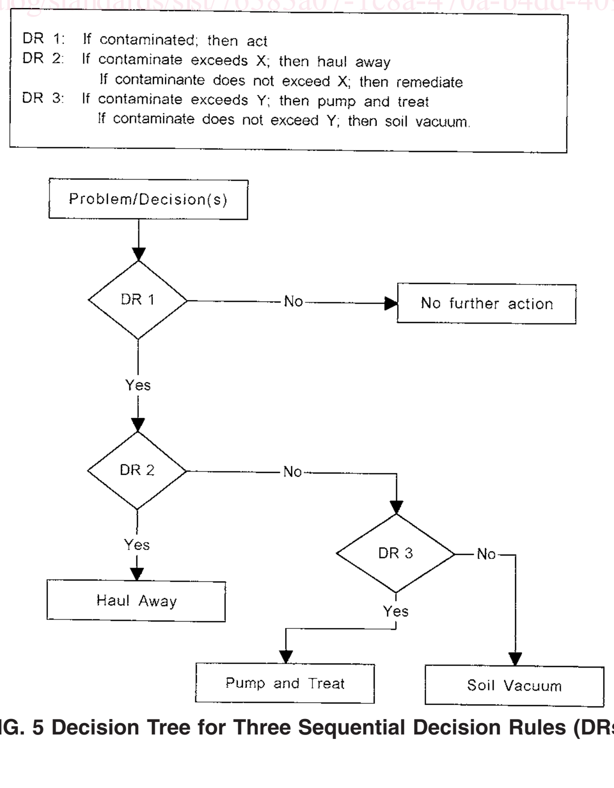

FIG. 5 Decision Tree for Three Sequential Decision Rules (DRs)