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Standard Practice for Derivation of Decision Point and Confidence Limit for Statistical Testing of Mean Concentration in Waste Management Decisions[1]

This standard is issued under the fixed designation D6250; 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 a logical basis for the derivation of a decision point and confidence limit when mean concentration is used for making environmental waste management decisions. The determination of a decision point or confidence limit should be made in the context of the defined problem. The main focus of this practice is on the determination of a decision point.

1.2 In environmental management decisions, the derivation of a decision point allows a direct comparison of a sample mean against this decision point, where similar decisions can be made by comparing a confidence limit against a concentration limit (for example, a regulatory limit, which will be used as a surrogate term for any concentration limit throughout this practice). This practice focuses on making environmental decisions using this kind of statistical comparison. Other factors, such as any qualitative information that may be important to decision-making, are not considered here.

1.3 A decision point is a concentration level statistically derived based on a specified decision error and is used in a decision rule for the purpose of choosing between alternative actions.

1.4 This practice derives the decision point and confidence limit in the framework of a statistical test of hypothesis under three different presumptions. The relationship between decision point and confidence limit is also described.

1.5 Determination of decision points and confidence limits for statistics other than mean concentration is not covered in this practice. This practice also assumes that the data are normally distributed. When this assumption does not apply, a transformation to normalize the data may be needed. If other statistical tests such as nonparametric methods are used in the decision rule, this practice may not apply. When there are many data points below the detection limit, the methods in this practice may not apply.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D5792 Practice for Generation of Environmental Data Related to Waste Management Activities: Development of Data Quality Objectives

D4790 Terminology of Aromatic Hydrocarbons and Related Chemicals

E456 Terminology Relating to Quality and Statistics

E1138 Terminology for Technical Aspects of Products Liability Litigation (Withdrawn 1995)[3]

2.2 *Other Documents:*

USEPA (1989a) Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities. Interim Final Guidance. Office of Solid Waste Management Division, Washington, D.C. (PB89-15-1047)[4]

USEPA (1989b) Methods for Evaluating the Attainment of Cleanup Standards. Vol. 1: Soils and Solid Media. Statistical Policy Branch (PM-223)[4]

USEPA (1992) Statistical Methods for Evaluating the attainment of Superfund Cleanup Standards. Vol. 2: Groundwater. DRAFT, Statistical Policy Branch, Washington, D.C[4]

USEPA (1994) Guidance for the Data Quality Objectives Process. EPA QA/G4, Quality Assurance Management Staff, USEPA, September, 1994[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *decision point, n*—the numerical value which causes the decision maker to choose one of the alternative actions (for example, conclusion of compliance or noncompliance).

[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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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3.1.1.1 *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, for example, 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.

3.1.2 *confidence limits, n*—the limits on either side of the mean value of a group of observations which will, in a stated fraction or percent of the cases, include the expected value. Thus the 95 % confidence limits are the values between which the population mean will be situated in 95 out of 100 cases. **D4790**

3.1.2.1 *Discussion*—A one-sided upper or lower confidence limit can also be used when appropriate. An upper confidence limit is a value below which the population mean is expected to be with the specified confidence. Similarly, a lower confidence limit is a value above which the population mean is expected to be with the specified confidence. It is to be noted that confidence limits are calculated after the collection of sample data.

3.1.3 *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. **D5792**

3.1.3.1 *Discussion*—For this practice, the comparison in (1) in 3.1.3 can be made in two equivalent ways: (*1*) a comparison between the sample mean (calculated from the sample data) and a decision point (calculated during the planning stage), or (*2*) a comparison between a confidence limit(s) (calculated from the sample data) and a regulatory limit.

3.1.4 *false negative error, n*—occurs when environmental data mislead decision maker(s) into not taking action specified by a decision rule when action should be taken. **D5792**

3.1.4.1 *Discussion*—For this practice, this is an error defined in the context of a regulatory decision in waste management. In this context, it is an error in concluding that the true value is smaller than the regulatory limit when in fact it is not. The calculation of the false negative error will depend on how the hypotheses are framed (see Appendix X1).

3.1.5 *false positive error, n*—occurs when environmental data mislead decision maker(s) into taking action specified by a decision rule when action should not be taken. **D5792**

3.1.5.1 *Discussion*—For this practice, this is an error defined in the context of a regulatory decision in waste management. In this context, it is an error in concluding that the true value is equal to or greater than the regulatory limit when in fact it is not. The calculation of the false positive error will depend on how the hypotheses are framed (see Appendix X1).

3.1.6 *hypothesis, n*—a supposition or conjecture put forward to account for certain facts and used as a basis for further investigation by which it may be proved or disproved. **E1138**

3.1.6.1 *Discussion*—For this practice, a hypothesis is a postulation of what the true value is, typically framed for the purpose of making a statistical test of the hypothesis. In a statistical test, there are two competing hypotheses: the null hypothesis and the alternative hypothesis. The null hypothesis is a hypothesis "put up" for consideration and is the presumed hypothesis of choice before the data are collected. The alternative hypothesis is favored only when the data reject the null hypothesis.

3.1.7 *statistic, n*—a quantity calculated from a sample of observations, most often to form an estimate of some population parameter. **E456**

4. Significance and Use

4.1 Environmental decisions often require the comparison of a statistic to a decision point or the comparison of a confidence limit to a regulatory limit to determine which of two alternate actions is the proper one to take.

4.2 This practice provides a logical basis for statistically deriving a decision point, or a confidence limit as an alternative, for different underlying presumptions.

4.3 This practice is useful to users of a planning process generally known as the data quality objectives (DQO) process (see Practice D5792), in which calculation of a decision point is needed for the decision rule.

5. Overview of Decision Point Determination

5.1 The determination of a decision point is usually a part of an overall planning process. For example, the decision rule in the DQO planning process often includes the specification of a decision point. A brief summary of the steps needed to determine a decision point is given below.

5.1.1 State the problem and the decision rule (see Section 6),

5.1.2 Consider the alternative presumptions in the hypotheses based on the relative consequences of false positive and false negative errors (see 7.6),

5.1.3 Choose the form of the hypotheses to be used in the decision rule based on the chosen presumption (see 7.5 through 7.6 and Fig. 1),

5.1.4 Obtain an estimated standard deviation and the number of samples used in that estimation,

5.1.5 Specify acceptable decision errors (see Section 8), and

5.1.6 Calculate the decision point (see Section 8).

5.2 The following sections discuss in practical terms the topics of decision rule, presumptions and test of hypothesis, calculation of a decision point for specified decision errors, ways to control decision errors, and the use of a confidence limit as an alternative approach in decision-making.

6. Decision Rule in Waste Management Decisions

6.1 A decision rule is constructed according to a problem statement defined and agreed to by all the parties concerned,

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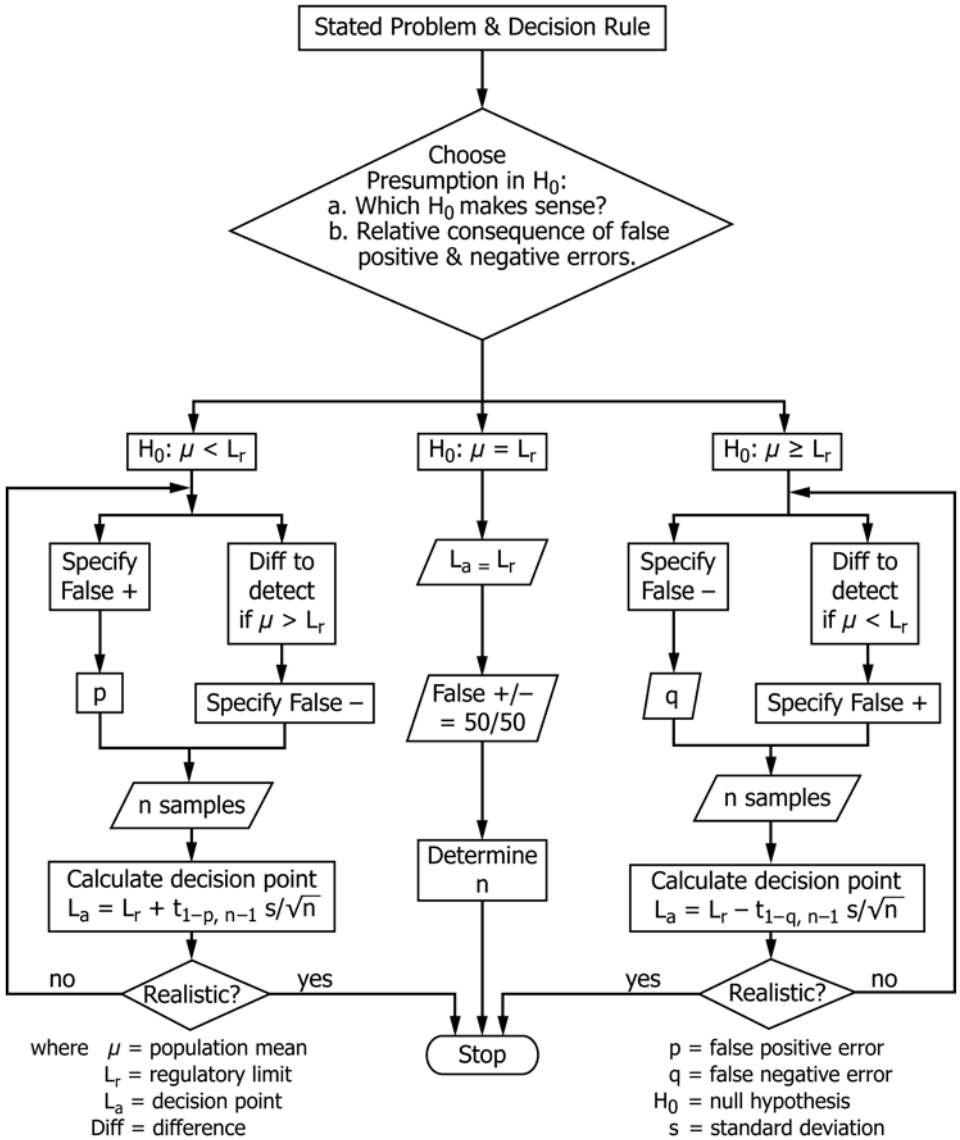

FIG. 1 Decision Point Determination for Mean Concentration

through a planning process. The decision rule can be carried out in two similar ways.

6.1.1 *When Using A Decision Point:*

6.1.1.1 The general construct of the decision rule in this case is:

If (sample mean) ≥ (decision point), then (one action).
Otherwise, (alternate action).

6.1.1.2 Because a decision point is needed in the above decision rule, this practice provides a logical basis for developing such a decision point. Because the above decision rule can also be carried out similarly using confidence limits, it is also presented that way in 6.2.

6.1.1.3 Note that when data can be measured with certainty, the regulatory limit defines the decision point. For example, sample data taken from a totally homogeneous population, in the absence of measurement error, have no variability. This means that the standard deviation of the data is zero and the decision point is reduced to the regulatory limit (see 8.6.3).

6.1.1.4 When data cannot be measured precisely or the population is not totally homogeneous, this variability needs to be incorporated to obtain a decision point. The decision point then includes both the original regulatory limit and a margin of uncertainty that is reflected in the standard deviation, which is a component in the calculation of the decision point (see 8.6.3). The way to incorporate this uncertainty depends on how a hypothesis is formulated and which presumption is adopted. This is discussed in Section 7.

6.1.1.5 An example of carrying out the decision rule using a decision point is:

If (average concentration of cadmium in a truck load) ≥ (decision point), then (dispose of the waste fly ash in an RCRA landfill).
Otherwise, (dispose the waste fly ash in a sanitary landfill).

6.1.1.6 The inputs needed for the calculation of the decision point in 6.1.1.5 are: form of the hypotheses to be tested, acceptable maximum decision error, number of samples, and estimated standard deviation. The standard deviation should

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include all the sources of variation in the sampling and measurement processes. Decision errors include the false positive error and false negative error. Details are given in Section 8.

6.2 *When Using Confidence Limit:*

6.2.1 The general construct of the decision rule in this case is:

$$\text{If (confidence limit)} > \text{or} < \text{(regulatory limit), then (one action)}$$
$$\text{Otherwise, (alternate action).}$$

where the confidence limit can be the upper confidence limit or the lower confidence limit, depending on the chosen presumption in the null hypothesis (see Section 7). A special case where the confidence limit is replaced by the sample mean in the above decision rule is also discussed in Section 7.

6.2.2 Two examples corresponding to the > and < signs in the decision rule are:

6.2.2.1 If upper confidence limit of mean concentration of cadmium) > (regulatory limit), then (dispose of the waste fly ash in a RCRA landfill). Otherwise, (dispose of the waste fly ash in a sanitary landfill).

6.2.2.2 If lower confidence limit of mean concentration of cadmium) < (background concentration), then (dispose of the waste fly ash in a sanitary landfill). Otherwise, (dispose of the waste fly ash in a RCRA landfill).

6.2.3 The relationship between the decision point approach and the confidence limit approach is described in Appendix X1.

6.2.4 The decision point approach and the confidence limit approach are identical in decision-making if the standard deviation (s) and number of samples (n) used in the calculations are identical. Since the decision point is calculated during the planning stage and before the sample data are collected, its s and n may be different from those used in the calculation of the confidence limit (which is calculated after the data are collected).

6.2.5 Note that similar to 6.1.1, when data can be measured with certainty, the confidence limit in the decision rule above is reduced to the sample mean, because the standard deviation of the data is zero (see 8.6.4).

7. Test of Hypothesis

7.1 This section is a brief introduction to the concept of statistical test of hypothesis and how it relates to the determination of a decision point.

7.2 A statistical test of hypothesis is framed by two hypotheses: a null hypothesis and an alternative hypothesis.

7.3 The null hypothesis is a hypothesis "put up for consideration" or "being tested." That is, the null hypothesis is presumed to be the hypothesis of choice before the data are collected. If, after the data are collected, the sample data are consistent with this hypothesis, then the null hypothesis is not rejected and the alternative hypothesis is discarded. If, on the other hand, the data are not consistent with the null hypothesis, then the null hypothesis is rejected in favor of the alternative hypothesis.

7.4 Thus, it is the alternative hypothesis that bears the "burden of proof." That is, the alternative hypothesis is not favored until the data suggest that the null hypothesis is not tenable and cause the rejection of the null hypothesis.

7.5 *Presumptions in Null Hypothesis*—In environmental testing, two presumptions can be postulated for the null hypothesis. A third presumption can be constructed as a compromise between the first two presumptions based on practical considerations.

7.5.1 *Presumption Number 1*—The true (population) mean concentration is presumed to be below the regulatory limit, with an opposite presumption in the alternative hypothesis.

7.5.1.1 This presumption of no exceedance would require" cleanup" down to a concentration level not statistically significantly higher than the regulatory limit. In this case, the decision point will be higher than the regulatory limit.

7.5.2 *Presumption Number 2*—The true (population) mean concentration is presumed to be equal to or greater than the regulatory limit, with an opposite presumption in the alternative hypothesis.

7.5.2.1 This presumption of exceedance would require" cleanup" down to a concentration level statistically significantly lower than the regulatory limit. In this case, the decision point will be lower than the regulatory limit.

7.5.3 *Presumption Number 3*—a neutral presumption that the true mean concentration is neither higher nor lower than the regulatory limit.

7.5.3.1 This presumption would require "cleanup" down to the regulatory limit. In this case, the decision point is identical to the regulatory limit.

7.5.3.2 This presumption is a compromise between the first two presumptions based on practical considerations. See X1.6 of Appendix X1 for details.

7.6 *Choice of Presumption*

7.6.1 The presumption of "exceedance over the regulatory limit" (Presumption 2) is a reasonable choice when the contaminants are highly toxic or when protection of health and environment is of first priority. However, it will tend to incur higher costs in environmental waste management.

7.6.2 The first presumption of "no exceedance" is considered reasonable for the following example situations.

7.6.2.1 When comparing environmental cleanup or remediation against background, cleanup below the background has little technical merit. For example, RCRA groundwater regulations stipulate use of the first presumption in the statistical comparisons (USEPA, 1989a).[4]

7.6.2.2 Frequently, the regulatory limit is arrived at with a series of assumptions. For example, the regulatory limit may be derived from animal data, and extrapolation is made to estimate human risk. Often the extrapolation chooses a set of data with the most severe health effects; uses a conservative model to extrapolate from the high dose response to the low dose response; uses conservative assumptions in extrapolating from animal risk to human risk; and uses conservative assumptions in estimating human exposure.

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(1) When this kind of conservatism is built into the regulatory limit, it is often unnecessary to impose the additional conservatism of the more strict presumption of "exceedance" in the null hypothesis.

7.6.2.3 When the regulatory limit is low or close to zero, use of the second presumption may lead to a decision point being negative or zero, which is impractical.

7.6.2.4 More fundamentally, the choice can be made by considering the decision errors and the severity of their consequences.

7.6.2.5 When the consequence of a false negative decision error is more severe than that of the false positive decision error, then the presumption of "exceedance over the regulatory limit" (Presumption 2) may be reasonable. When the consequence of a false positive decision error is more severe than that of the false negative decision error, then the presumption of "no exceedance over the regulatory limit" (Presumption 1) may be reasonable. When neither decision error seems to be dominant, then a neutral presumption (Presumption 3) may be reasonable. It is by weighing the decision errors and their respective consequences that a reasonable presumption can be reached.

7.6.2.6 At times, choice of a presumption is mandated by regulations.

8. Determination of A Decision Point

8.1 An overview of how a decision point is derived is given in Section 5. This section provides the details.

8.2 Fig. 1 provides a schematic description of how a decision point is derived within the framework of hypothesis testing under different presumptions in the null hypothesis. The left-hand side of Fig. 1 corresponds to 8.6, the right-hand side to 8.7, and the middle part of Fig. 1 to 8.8. Paragraphs 8.6 through 8.8 also show how the decision rules can be carried out similarly using either the decision point or confidence limit approach. Note that all the boxes here apply to the confidence limit approach, while only some of the boxes apply to the decision point approach. Details are discussed in the appropriate following sections.

8.3 The mathematical details for deriving a decision point or a confidence limit are given in Appendix X1. Normal distribution of the data is assumed throughout this practice. When the data are not normally distributed, a transformation to normalize the data may be necessary. Other statistical tests for non-normal data can also be used, but they will not be covered here.

8.4 Note that when formulating the decision rule during the planning process, the decision point is calculated before the data are collected from a formal sampling plan. As can be seen from Eq 4 and 6, values for the standard deviation, s, and the number of samples, n, need to be provided for this calculation. They can come from previously available data. If existing data are limited or non-existent, a pilot study to obtain this information may be necessary. In any event, if the values of s and n so obtained are crude, the derived decision point will be only an approximation. If this approximation is sufficient for testing purposes, the test can proceed. If not, either a pilot study needs to be conducted or the confidence limit approach can be used in place of the decision point approach. Since the confidence limit is calculated after the data are collected, s and n are readily available.

8.5 The previous observations apply to all three cases of presumptions.

8.6 *First Presumption—True Mean Concentration Is Below the Regulatory Limit:*

8.6.1 The statistical test of whether or not the true mean concentration exceeds the regulatory limit can be carried out similarly using either the decision point or the confidence limit. Determination of a decision point under this presumption is schematically given in Fig. 1 (left-hand side of figure).

8.6.2 The relationships between the decision to "accept" a certain hypothesis and the associated decision errors under this presumption are given in Fig. 2.

8.6.3 *Using a Decision Point in the Decision Rule:*

8.6.3.1 Under this presumption, the decision point L_a can be calculated as follows:

$$L_a = L_r + t_{1-p,n-1} s/\sqrt{n} \quad (1)$$

where:

L_a = decision point,
L_r = regulatory limit,
$t_{1\text{-p},n\text{-}1}$ = tabled t-value with 100p % false positive error and (n-1) degrees of freedom,
p = specified maximum false positive error (in fraction) and is typically a number smaller than 0.5,
s = estimated standard deviation, and
n = number of samples in the estimation of s.

8.6.3.2 The steps in the statistical test are as follows:

(1) Before the sample data are collected: Specify the statistical comparison in the decision rule. Specify the two alternative actions in the decision rule. Specify the maximum acceptable false positive error p, $p < 0.5$. For given number of samples (n), estimated standard deviation (s), regulatory limit (L_r) and tabled t-value, calculate the decision point L_a according to Eq 1. If the calculated L_a is realistic, a decision point has been determined. If not, the previous steps can be reiterated for different values of acceptable false positive error (p). Note that the number of samples (n) and standard deviation (s) are given values. However, different values of s or n, or both, may be tried for scenario analysis. The reiteration may need to go back to earlier steps, including restating the problem.

(2) After the sample data are collected, Calculate the sample mean $\bar{x}$. Compare $\bar{x}$ to L_a. If $\bar{x} \geq L_a$, conclude that the regulatory limit has been exceeded and take one course of action in the decision rule. Otherwise, conclude differently and take the alternate action.

8.6.4 *Using a Confidence Limit in the Decision Rule:*

8.6.4.1 Under this presumption, the 100 (1-p) % lower confidence limit (LCL), associated with a 100p % false positive error and corresponding to the decision point in Eq 1 is:

$$\text{LCL} = \bar{x} - t_{1-p,n-1} s/\sqrt{n} \quad (2)$$

8.6.4.2 The steps in the statistical test are as follows:

(1) Before the sample data are collected: Specify the statistical comparison in the decision rule. Specify the two

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