



# Standard Practice for Derivation of Decision Point and Confidence Limit for Statistical Testing of Mean Concentration in Waste Management Decisions<sup>1</sup>

This standard is issued under the fixed designation D 6250; 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 ( $\epsilon$ ) 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:*

- D 4687 Guide for General Planning of Waste Sampling<sup>2</sup>
- D 5792 Practice for Generation of Environmental Data Related to Waste Management Activities: Development of Data Quality Objectives<sup>2</sup>
- D 4790 Terminology of Aromatic Hydrocarbons and Related Chemicals<sup>3</sup>
- E 456 Terminology Relating to Quality and Statistics<sup>4</sup>
- E 1138 Terminology of Technical Aspects of Products Liability Litigation<sup>4</sup>

### 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)<sup>5</sup>
- USEPA (1989b) Methods for Evaluating the Attainment of Cleanup Standards. Vol. 1: Soils and Solid Media. Statistical Policy Branch (PM-223)<sup>5</sup>
- USEPA (1992) Statistical Methods for Evaluating the attainment of Superfund Cleanup Standards. Vol. 2: Groundwater. DRAFT, Statistical Policy Branch, Washington, D.C.<sup>5</sup>
- USEPA (1994) Guidance for the Data Quality Objectives Process. EPA QA/G4, Quality Assurance Management Staff, USEPA, September, 1994<sup>5</sup>

## 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).

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

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 11.04.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 06.04.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 14.02.

<sup>5</sup> Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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.

**D 4790**

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.

**D 5792**

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.

**D 5792**

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.

**D 5792**

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.

**E 1138**

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.

**E 456**

## 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 D 5792), 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, 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)  $\geq$  (decision point), then (one action). Otherwise, (alternate action).

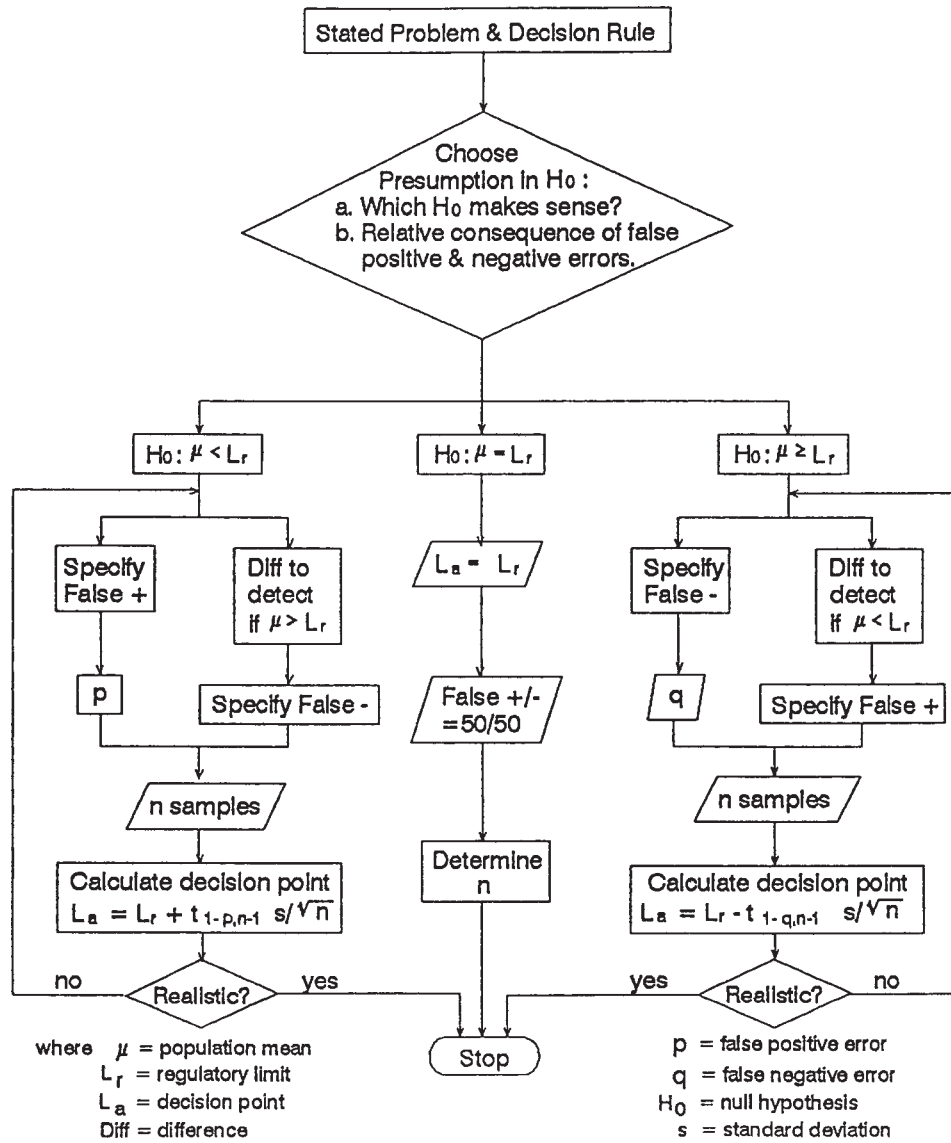


FIG. 1 Decision Point Determination for Mean Concentration

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)  $\geq$  (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 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:

If (confidence limit)  $>$  or  $<$  (regulatory limit), then (one action)  
 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).<sup>5</sup>

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.

7.6.2.2.1 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,
- $t_{1-p, n-1}$  = 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:

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

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 alternative actions in the decision rule. Specify the maximum acceptable false positive error  $p$ , where  $p < 0.5$ .

(2) After the sample data are collected, Calculate the lower confidence limit (LCL) in accordance with Eq 2. Compare the LCL to the regulatory limit  $L_r$ . If  $LCL \geq L_r$ , conclude that the regulatory limit has been exceeded and take one course of action. Otherwise, conclude differently and take the alternate action.

8.6.4.3 Application of the decision rule under Presumption Number 1 using either a decision point or a lower confidence limit is given graphically in Fig. 3.

NOTE 1—Although specification of the false negative error is not needed for the calculation of a decision point or a confidence limit, such specification is necessary to determine the number of samples needed to achieve the desired false negative error. This subject is beyond the scope of this practice and is not covered.

8.6.4.4 In confidence limit approach, the determination of how many samples to collect does require inputs such as false

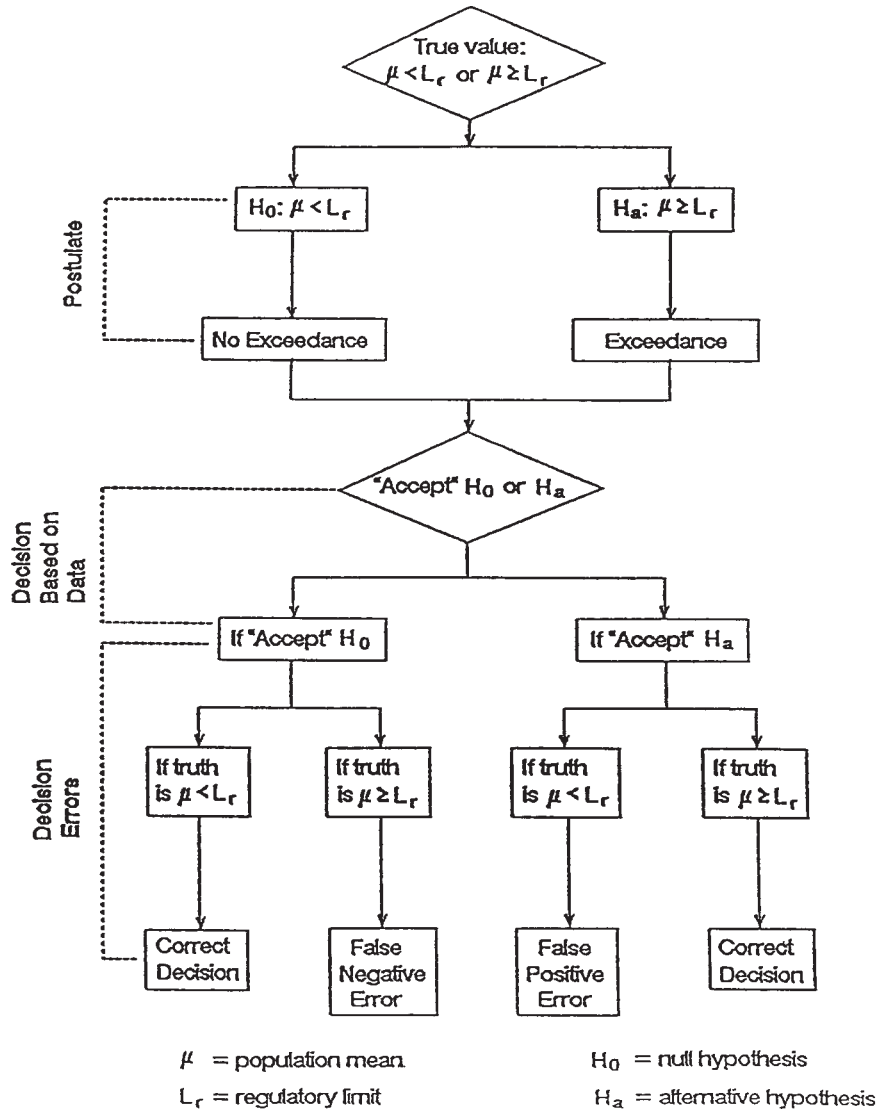


FIG. 2 Relationships Between Hypotheses and Decision Errors Under First Presumption

positive error, false negative error, and a difference from the hypothesized value (in the null hypothesis) important to detect. These inputs are described in the left hand side of Fig. 1. Specifics regarding determination of the number of samples is not covered in this practice.

8.6.4.5 Some example criteria for judging whether a derived decision point is realistic or not could include: (1) Does the value of the decision point make sense? A decision point that is below the detection limit or negative is unlikely to be useful. (2) Does the decision point reflect a good balance between the potential consequences of the two types of decision errors? A decision point that leads to either unaffordable costs or a consequence of high toxicity or other adverse effects needs to be re-examined carefully.

8.6.4.6 Note that the decision point given in Eq 1 includes both the regulatory limit and the uncertainty in the data. When the data are measured with certainty, the standard deviation,  $s$ , becomes zero, and the regulatory limit becomes the decision point.

8.7 Second Presumption—True Mean Concentration Is Equal to or Higher Than the Regulatory Limit:

8.7.1 Again, 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.

8.7.2 Determination of a decision point under this presumption is schematically given in Fig. 1 (right hand side of figure).

8.7.3 The relationships between the decision to “accept” a certain hypothesis and the associated decision errors, under this presumption, are given in Fig. 4.

8.7.4 Using a Decision Point in the Decision Rule:

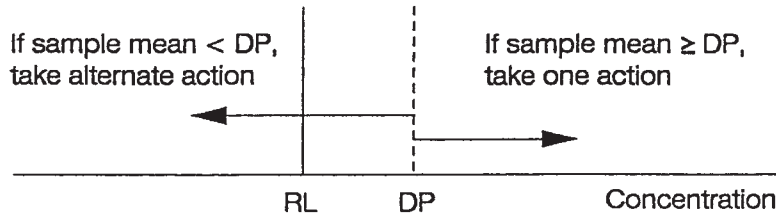
8.7.4.1 Under this presumption, the decision point  $L_a$  can be calculated as follows:

$$L_a = L_r - t_{1-q, n-1} s / \sqrt{n} \tag{3}$$

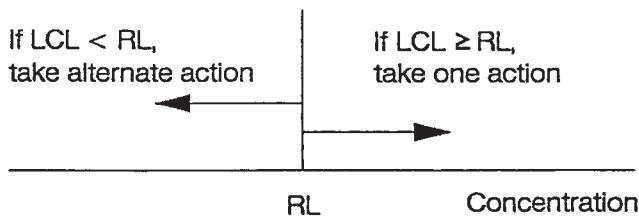
where:

$q$  = specified maximum acceptable false negative error (in fraction), where  $q < 0.5$ .

a. When using an decision point (DP)



b. When using lower confidence limit (LCL)



RL = regulatory limit

FIG. 3 Application of Decision Rules Under Presumption Number 1

8.7.4.2 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 alternative actions in the decision rule. Specify acceptable maximum false negative error  $q$ ,  $q < 0.5$ . For given number of samples ( $n$ ), estimated standard deviation ( $s$ ), regulatory limit ( $L_r$ ) and tabled  $t$ -value, calculate the decision point  $L_a$  in accordance with Eq 3. If the calculated  $L_a$  is realistic, a decision point has been determined. If not, the previous steps can be reiterated, including trying different values of acceptable false negative error ( $q$ ). Note that the number of samples ( $n$ ) and standard deviation ( $s$ ) are given values. However, different values of  $s$  or  $n$ , or both, can be tried for scenario analysis.

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

8.7.5 Using a Confidence Limit in the Decision Rule:

8.7.5.1 The 100 (1- $q$ ) % upper confidence limit (UCL), associated with a 100 $q$  % false negative error and corresponding to the decision point in Eq 3 is:

$$UCL = \bar{x} + t_{1-q,n-1}s/\sqrt{n} \quad (4)$$

8.7.5.2 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 acceptable maximum false negative error  $q$ ,  $q < 0.5$ .

(2) After the sample data are collected, Calculate the upper confidence limit (UCL) in accordance with Eq 4. Compare the UCL to the regulatory limit  $L_r$ . If  $UCL \geq L_r$ , then conclude that the regulatory limit has been exceeded and take one course of action. Otherwise, conclude differently and take the alternate action.

8.7.5.3 Application of the decision rules under Presumption Number 2 using either a decision point or an upper confidence limit, is given graphically in Fig. 5.

NOTE 2—Although specification of the false positive error is not needed for the calculation of a decision point or a confidence limit here, such specification is necessary to determine the number of samples needed to achieve the desired false positive error. This subject is beyond the scope of this document and is not covered.

8.7.5.4 In confidence limit approach, the determination of how many samples to collect does require inputs such as false positive error, false negative error and a difference from the hypothesized value (in the null hypothesis) important to detect. These inputs are described in the right side of Fig. 1. Specifics regarding determination of the number of samples is not covered in this standard.

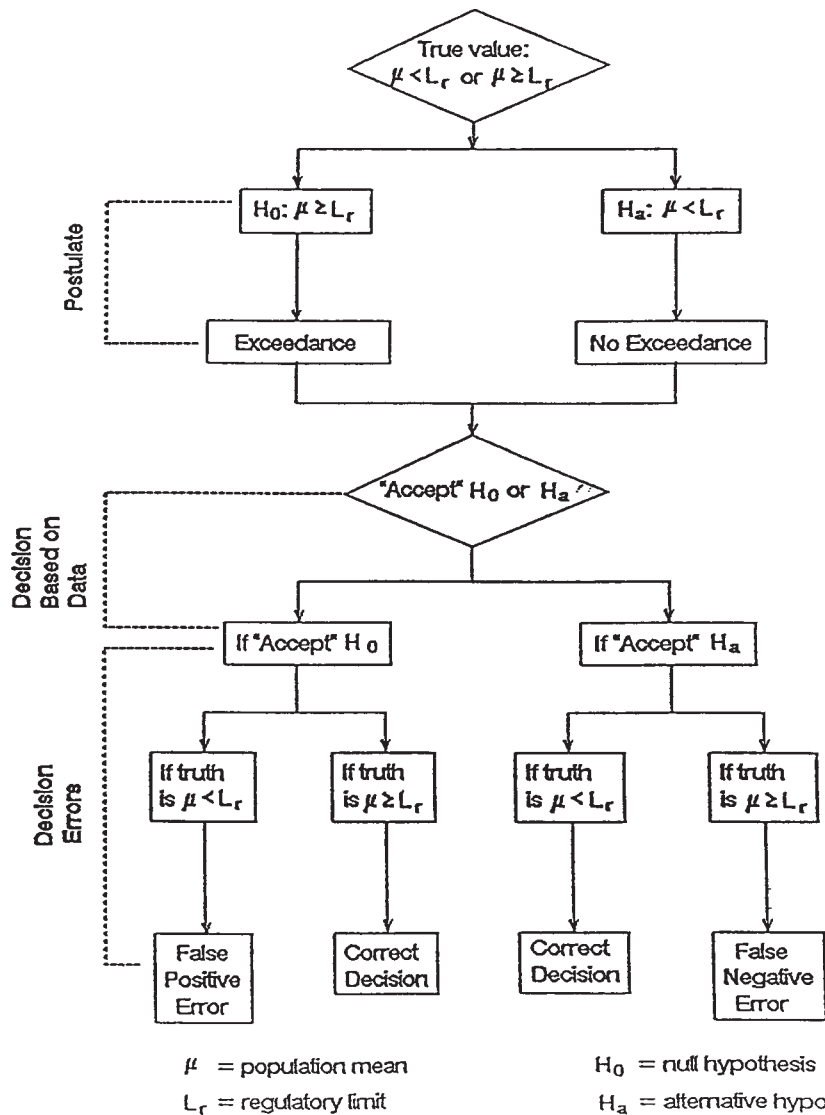


FIG. 4 Relationships Between Hypotheses and Decision Errors Under Second Presumption

8.7.5.5 Other comments in Note 1 on judging how realistic a calculated decision point may also apply here.

(1) Note that the decision point given in Eq 2 includes both the regulatory limit and the uncertainty in the data. When the data are measured with certainty, the standard deviation  $s$  becomes zero and the regulatory limit becomes the decision point.

8.8 Third Presumption—True Mean Concentration Is neither Higher nor Lower Than the Regulatory Limit:

8.8.1 In this case, the statistical test is the same for either the decision point approach or the confidence limit approach.

8.8.2 Under this presumption, the decision point  $L_a$  is the regulatory limit  $L_r$  (see X1.6 of Appendix X1 for details). Namely,

$$L_a = L_r \quad (5)$$

8.8.3 The steps in the statistical test are as follows:

8.8.3.1 Before the sample data are collected:

(1) Specify the statistical comparison in the decision rule as a comparison between  $x$  and  $L_r$ .

(2) Specify the two alternative actions in the decision rule.

8.8.3.2 After the sample data are collected:

(1) Calculate the sample mean  $x$ .

(2) Compare  $x$  to  $L_r$ . If  $x \geq L_r$ , conclude that the regulatory limit has been exceeded and take one course of action. Otherwise, conclude differently and take the alternate action.

8.8.4 Note that the false positive error and the false negative error are equal, at 50 % each, when the true value is at the regulatory limit (see Appendix X1).

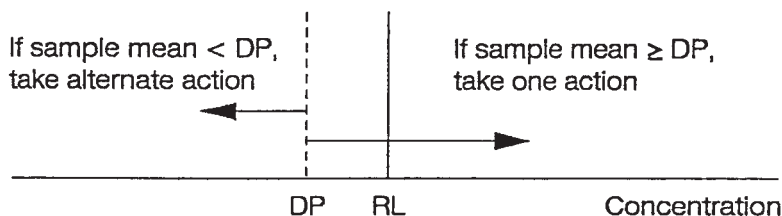
8.8.5 Application of the decision rule under Presumption Number 3 is similar to Fig. 3 and Fig. 5. In this case, the decision rule is a simple comparison between the sample mean concentration  $x$  and the regulatory limit  $L_r$ .

## 9. Control of Decision Errors

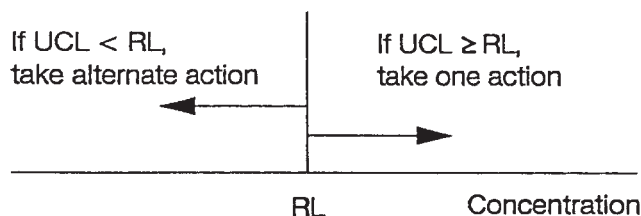
9.1 Note that an environmental decision involves two parts:

(1) the true relationship (or relative positions) between the population mean concentration (true value) and the regulatory

a. When using an decision point (DP)



b. When using upper confidence limit (UCL)



RL = regulatory limit

FIG. 5 Application of Decision Rules Under Presumption Number 2

limit, and (2) a conclusion on this relationship based on empirical data. A decision error of false positive or false negative is made only when the two parts are in conflict (see Fig. 3 and Fig. 5).

9.2 A false positive error is made when an empirical conclusion of the true mean concentration being higher than the regulatory limit is made when the true relationship is otherwise. Similarly, a false negative error is made when an empirical conclusion of the true mean concentration being lower than the regulatory limit is made when the true relationship is otherwise.

9.3 Because both kinds of decision errors are anchored at the regulatory limit, it is important to know what the decision error rate is when the true mean concentration is around the regulatory limit. Details are given in Appendix X1.

9.4 Control of decision errors is addressed according to the underlying presumptions.

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

9.5.1 Under this presumption, the acceptable maximum false positive decision error is specified first. It is usually specified based on negotiated agreement by the concerned parties after considering the risk and consequence of the error and the costs necessary to control the error to the specified level. When the true value is at the regulatory limit, the corresponding false negative error is 100 % minus the specified false positive error (in percent).

9.5.2 The second step is to control the false negative error by any of the following:

9.5.2.1 Reducing the variance of the sample data. The smaller the variance is, the lower the false negative error is, all other things (such as the decision point and regulatory limit) being the same. This can be accomplished, for example, by reducing the variance due to sampling or measurement, or both, and compositing of the samples.

9.5.2.2 Increasing the number of samples. This needs to be weighed against the increase in sampling and analytical costs. If composite samples are used, the increase in costs may be controlled.

9.5.2.3 Specifying an allowable increment in concentration from the regulatory limit which is important to detect statistically.

(1) When this increment is zero, then the false negative error is exactly the complement of the specified false positive error. Namely, they total 100 %.

(2) If, on the other hand, there is some flexibility in the decision rule, then the increment could be defined as an increase above the regulatory limit which would not pose a substantial increase in health or environmental risk, but an increase beyond that would. If such is the case, then a false negative error is defined as the probability of failing to detect such an increase. As a matter of fact, false negative errors associated with different increments from the regulatory limit can be calculated for scenario analysis (see Appendix X1).

**9.6 Second Presumption—True Mean Concentration Is Equal to or Higher Than the Regulatory Limit:**

9.6.1 Under this presumption, the acceptable maximum false negative decision error is specified first. It is usually specified based on negotiated agreement by the concerned parties after considering the risk and consequence of the error and the costs necessary to control the error to the specified level. When the true value is at the regulatory limit, the corresponding false positive error is 100 % minus the specified false negative error (in percent).

9.6.2 False positive error can then be controlled by any of the following:

9.6.2.1 Reducing the variance of the sample data. The smaller the variance is, the lower the false positive error is, all other things (such as the decision point and regulatory limit) being the same. This can be accomplished, for example, by reducing the variance due to sampling or measurement variance, or both, and compositing of the samples.

9.6.2.2 Increasing the number of samples. This needs to be weighed against the increase in sampling and analytical costs. If composite samples are used, the increase in costs may be controlled.

9.6.2.3 Specifying an allowable decrement in concentration from the regulatory limit which is important to detect statistically.

(1) When this decrement is zero, then the false positive error is the exact complement of the specified false negative error. Namely, they total 100 %.

(2) If, on the other hand, there is some flexibility in the decision rule, then the decrement could be defined as a decrease below the regulatory limit which would not pose a substantial increase in cleanup or remediation costs, but a decrease beyond that would. If such is the case, then a false positive error can be defined as the probability of failing to detect such a decrement. As a matter of fact, false positive errors can be calculated for different decrements below the regulatory limit for scenario analysis (see Appendix X1).

**9.7 Third Presumption—True Mean Concentration Is Neither Higher nor Lower Than the Regulatory Limit:**

9.7.1 Under this presumption, the false positive and false negative errors are equal at 50 % each when the true value is at the regulatory limit.

9.7.2 In this case, the reduction in variance and the increase in the number of samples do not actually change the probabilities of false positive and false negative errors. However, they do tighten the distribution of the sample data such that there is less uncertainty in the decision. Namely, a smaller variance will allow statistical detection of a smaller deviation from the regulatory limit.

**10. Keywords**

10.1 confidence limit; data quality objectives; decision error; decision point; false negative; false positive; hypothesis; mean concentration; presumption; waste management

**APPENDIX**

**(Nonmandatory Information)**

**X1. MATHEMATICAL DERIVATION OF A DECISION POINT FROM STATISTICAL TEST OF HYPOTHESIS FOR MEAN CONCENTRATION**

X1.1 The derivation of a decision point has the purpose of statistically testing if the true mean concentration of a well-defined population exceeds the regulatory limit, using sample data taken from the population.

X1.2 The decision point  $L_a$  can be derived from a statistical test of hypothesis under three different presumptions.

X1.2.1 *Decision Point Derivation Under First Presumption*—The true (population) mean concentration is presumed to be below the regulatory limit.

X1.2.1.1 The steps in deriving a decision point under this presumption are given in Fig. 1 (left hand side of figure).

X1.2.1.2 Under this presumption, the null and alternative hypotheses are:

$$H_o: u < L_r \text{ versus } H_a: u \geq L_r \quad (X1.1)$$

where:

$H_o$  = null hypothesis,

$H_a$  = alternative hypothesis,

$u$  = true (population) mean concentration, and

$L_r$  = regulatory limit.

X1.2.1.3 Associated with the null hypothesis above, the primary concern is the false positive error. A false positive decision error is the probability of concluding that the true concentration is greater than the regulatory limit when in fact it is not so. Note that in the decision rule, such a conclusion is reached only when  $x \geq L_a$ , where  $L_a$  is the decision point (see 8.6.3). Namely,

False positive error:

$$\begin{aligned} &= \text{probability of saying} \\ &\text{that the true mean concentration is not lower} \\ &\text{than the regulatory limit when it is so,} \\ &= \text{probability that the data observe } (\bar{x} \\ &\quad \geq L_a) \text{ in favor of } H_a \text{ when } H_o \text{ is the correct one,} \\ &= \text{Prob}(\text{rejecting } H_o \mid \text{when } H_o \text{ is true}), \text{ and} \\ &= \text{Prob}(\bar{x} (\geq L_a \mid H_o)). \end{aligned} \quad (X1.2)$$

X1.2.1.4 An acceptable maximum false positive error,  $p$ , can be specified so that it cannot be exceeded. Given this specification, the above expression becomes:

$$\text{Prob}(\bar{x} \geq L_a | H_o) \leq p \tag{X1.3}$$

X1.2.1.5 Generally,  $x$  in Eq X1.3 can be assumed to follow a normal distribution due to the central limit theorem in statistics (when the number of samples is relatively large). Namely,  $x$  can be assumed to follow a normal distribution with variance  $\sigma^2/n$  and a mean concentration below the regulatory limit under the null hypothesis  $H_o$ . In some cases, a transformation of the data may be necessary for the normality assumption to apply.

X1.2.1.6 Since the null hypothesis can be rewritten as  $H_o: \mu = L_r - \delta_1$ ,  $\delta_1 > 0$ , the false positive error in Eq X1.3 becomes:  

$$\text{Prob}(\bar{x} \geq L_a) = \text{Prob}\{[\bar{x} - (L_r - \delta_1)] / (\sigma/\sqrt{n}) \geq [L_a - (L_r - \delta_1)] / (\sigma/\sqrt{n})\} \tag{X1.4}$$

$$< \text{Prob}\{Z \geq (L_a - L_r) / (\sigma/\sqrt{n})\} = p, \text{ since } \delta_1 > 0$$

where  $Z$  is normally distributed with mean zero and variance 1, and  $n$  is the number of samples.

X1.2.1.7 Given Eq X1.4, the decision rule in a statistical test of hypothesis can be used to derive the decision point. The decision rule in test of hypothesis, for  $p < 0.5$ , is:

(1) If  $(L_a - L_r) / (\sigma/\sqrt{n}) \geq Z_{1-p}$ , then reject  $H_o$  and “accept” the alternative hypothesis of exceedance over the regulatory limit.

(2) If  $(L_a - L_r) / (\sigma/\sqrt{n}) < Z_{1-p}$ , then “accept” the null hypothesis  $H_o$  of no exceedance over the regulatory limit.

X1.2.1.8 The decision point is the cutoff point in this decision. Namely, set:

$$(L_a - L_r) / (\sigma/\sqrt{n}) = Z_{1-p} \tag{X1.5}$$

X1.2.1.9 Rearranging Eq X1.5, we obtain the decision point  $L_a$  for the hypotheses in Eq X1.1. Namely,

$$L_a = L_r + Z_{1-p} \sigma/\sqrt{n} \tag{X1.6}$$

X1.2.1.10 Eq X1.6 can be used to obtain the decision point  $L_a$  in the decision rule if the population standard deviation,  $\sigma$ , is known. When the population standard deviation,  $\sigma$ , is not known, its estimate  $s$  needs to be used and the decision point is given by Eq X1.7:

$$L_a = L_r + t_{1-p, n-1} s/\sqrt{n} \tag{X1.7}$$

where  $s$  is the estimated standard deviation, and  $t_{1-p, n-1}$  a tabled  $t$ -value with  $(n-1)$  degrees of freedom.

X1.2.1.11 Since the term  $(t_{1-p, n-1} s/\sqrt{n})$  in Eq X1.7 is non-negative, the decision point  $L_a$  is equal to or greater than the regulatory limit  $L_r$ .

X1.2.1.12 The decision rule using the decision point in Eq X1.7 is carried out as follows:

(1) If  $x < L_a$ , then do not reject  $H_o$  and conclude no exceedance over the regulatory limit.

(2) If  $x \geq L_a$ , then reject the null hypothesis  $H_o$  and conclude exceedance over the regulatory limit.

### X1.3 False Negative Decision Error:

X1.3.1 The corresponding false negative error under this presumption can be similarly calculated. Note that the alternative hypothesis can be rewritten as  $H_a: \mu = L_r + \delta_2$ ,  $\delta_2 \geq 0$ . Thus,

False negative decision error:

$$= \text{Probability of saying that the true mean concentration is lower than the regulatory limit when it is not so,} \tag{X1.8}$$

= Probability that the data observe ( $\bar{x} < L_a$ ) in favor of the null hypothesis  $H_o$  when the alternative hypothesis  $H_a$  is the correct one,

$$= \text{Prob}(\bar{x} < L_a | H_a),$$

$$= \text{Prob}\{Z < [L_a - (L_r + \delta_2)] / (\sigma/\sqrt{n})\}, \text{ and}$$

$$= \text{Prob}\{Z < Z_{1-p} - \delta_2/(\sigma/\sqrt{n})\}.$$

where  $Z_{1-p} = (L_a - L_r)/(\sigma/\sqrt{n})$  from Eq X1.5, and  $\delta_2 \geq 0$ ,  $p < 0.5$ .

X1.3.2 As can be seen above, false negative error is a function of how much the true mean  $\mu$  is higher than the regulatory limit  $L_r$ . This difference is  $\delta_2$  expressed in the unit of the standard error of the mean ( $\sigma/\sqrt{n}$ ), or altogether  $\delta_2/(\sigma/\sqrt{n})$ .

X1.3.3 False negative error rates, using Eq X1.8, for different values of  $\delta_2/(\sigma/\sqrt{n})$  are given in Table X1.1. When  $\delta_2/(\sigma/\sqrt{n}) = 0$ , the true value is right where the regulatory limit,  $L_r$ , is. As the true value becomes larger than  $L_r$  (when  $\delta_2/(\sigma/\sqrt{n}) > 0$ ), the false negative error becomes smaller.

X1.3.4 It is to be noted that the false negative error is the exact complement of the chosen false positive error when the true value is at  $L_r$ ; there the two errors total 100 %.

X1.3.5 When the population standard deviation,  $\sigma$ , is replaced by sample standard deviation,  $s$ , in Eq X1.8, the  $z$ -statistic is replaced by the  $t$ -statistic. The calculation of the false negative error now involves a non-centrality parameter and a statistician needs to be consulted.

### X1.4 Equivalency Between Decision Point Approach and Test of Hypothesis Approach:

X1.4.1 The decision rule using the decision point given in Eq X1.7 can be made to be equivalent to one using the lower 100 (1- $p$ ) % confidence limit in a statistical test of hypothesis.

X1.4.2 Recall that the decision rule using a decision point is to conclude exceedance of the regulatory limit if  $x \geq L_a$ .

X1.4.3 But  $L_a = L_r + t_{1-p, n-1} s/\sqrt{n}$ , from Eq X1.7. Thus  $x \geq L_a$  becomes  $x \geq L_r + t_{1-p, n-1} s/\sqrt{n}$ .

X1.4.3.1 Rearranging:

$$\bar{x} - t_{1-p, n-1} s/\sqrt{n} \geq L_r \tag{X1.9}$$

TABLE X1.1 False Negative Error ( $q$ ) Under Presumption Number 1

NOTE 1—For Some Values of False Positive Error ( $p$ ), and True Values  $\delta_2/(\sigma/\sqrt{n})$ .<sup>A</sup>

False Positive Error, $p$	If True Value As Number of Standard Errors Away from Regulatory Limit, or $\delta_2/(\sigma/\sqrt{n})$ , Is	False Negative Error, $q$
0.05	0	0.95
	1	0.74
	2	0.36
0.10	3	0.09
	0	0.90
	1	0.61
0.20	2	0.24
	3	0.04
	0	0.80
	1	0.44
	2	0.12
	3	0.02

<sup>A</sup> Where the true value = regulatory limit when  $\delta_2/(\sigma/\sqrt{n}) = 0$ .

X1.4.3.2 Note that the left-hand side of Eq X1.9 is the lower 100 (1-p) % confidence limit in the framework of a test of hypothesis. Thus, the decision point approach from Eq X1.7 and the hypothesis test approach from Eq X1.9 are equivalent in decision-making.

X1.4.3.3 The decision rule using the lower confidence limit in Eq X1.9 is carried out as follows:

(1) If  $(x - t_{1-p,n-1}s/\sqrt{n}) < L_r$ , then do not reject  $H_o$  and conclude no exceedance over the regulatory limit.

(2) If  $(x - t_{1-p,n-1}s/\sqrt{n}) \geq L_r$ , reject the null hypothesis  $H_o$  and conclude exceedance over the regulatory limit.

**X1.5 Decision Point Derivation Under Second Presumption**—The true (population) mean concentration is presumed to be equal to or greater than the regulatory limit.

X1.5.1 The steps in deriving a decision point under this presumption are given in Fig. 1 (right hand side of figure).

X1.5.2 Under this presumption, the null and alternative hypotheses are:

$$H_o : u \geq L_r \text{ versus } H_a : u < L_r \quad (\text{X1.10})$$

X1.5.3 Associated with the null hypothesis in X1.5.2, the primary concern is the false negative error. A false negative error is the probability of concluding that the true concentration is lower than the regulatory limit when in fact it is not so. Note that in the decision rule, such a conclusion is reached only when  $x < L_a$ , where  $L_a$  is the decision point (see 8.7.4). Namely,

False negative decision error:

$$\begin{aligned} &= \text{probability of saying} \\ &\text{that the true mean concentration is lower than} \\ &\text{the regulatory limit when it is not so,} \\ &= \text{probability that the data observe } (\bar{x} < L_a) \text{ in favor of} \\ &H_a \text{ when } H_o \text{ is the correct one,} \\ &= \text{Prob}(\text{rejecting } H_o | H_o), \text{ and} \\ &= \text{Prob}(\bar{x} < L_a | H_o). \end{aligned} \quad (\text{X1.11})$$

X1.5.4 An acceptable maximum false negative error,  $q$ , can be specified so that it cannot be exceeded. Given this specification, the Eq X1.11 becomes:

$$\text{Prob}(\bar{x} < L_a | H_o) \leq q \quad (\text{X1.12})$$

X1.5.5 The left-hand side of Eq X1.12 can be expanded under normal theory or the central limit theorem in statistics. Namely, under the null hypothesis  $H_o$ ,  $\bar{x}$  can be assumed to follow a normal distribution with variance  $\sigma^2/n$  and some mean concentration above the regulatory limit. Namely, the null hypothesis can be rewritten as  $H_o : u = L_r + \delta_3$ ,  $\delta_3 \geq 0$ .

X1.5.5.1 Thus, the false negative error in Eq X1.12 becomes:

$$\text{Prob}(\bar{x} < L_a) = \text{Prob}\{[\bar{x} - (L_r + \delta_3)]/(\sigma/\sqrt{n}) < [L_a - (L_r + \delta_3)]/(\sigma/\sqrt{n})\} \quad (\text{X1.13})$$

$$\leq \text{Prob}\{Z < (L_a - L_r)/(\sigma/\sqrt{n})\} = q$$

where  $Z$  is normally distributed with mean zero and variance 1,  $n$ , is the number of samples, and  $q < 0.5$ .

X1.5.6 Given Eq X1.13, the decision rule in statistical test of hypothesis is:

X1.5.6.1 If  $(L_a - L_r)/(\sigma/\sqrt{n}) < -Z_{1-q}$ , then reject  $H_o$  and “accept” the alternative hypothesis of no exceedance over the regulatory limit (for  $q < 0.5$ ).

X1.5.6.2 If  $(L_a - L_r)/(\sigma/\sqrt{n}) \geq -Z_{1-q}$ , then “accept” the null hypothesis,  $H_o$ , of exceedance over the regulatory limit.

X1.5.7 The decision point is the cutoff point in this decision. Namely,

$$(L_a - L_r) / (\sigma/\sqrt{n}) = Z_{1-q} \quad (\text{X1.14})$$

X1.5.8 Rearranging Eq X1.14, we obtain the decision point  $L_a$  for the hypotheses in Eq X1.10. Namely,

$$L_a = L_r - Z_{1-q}\sigma/\sqrt{n} \quad (\text{X1.15})$$

X1.5.9 Eq X1.15 can be used to obtain the decision point  $L_a$  in the decision rule if the population standard deviation,  $\sigma$ , is known. When the population standard deviation,  $\sigma$ , is not known, its estimate  $s$  needs to be used and the decision point is given by Eq X1.16:

$$L_a = L_r - t_{1-q,n-1}s/\sqrt{n} \quad (\text{X1.16})$$

where  $s$  is the estimated standard deviation, and  $t_{1-q,n-1}$  a tabled t-value with  $(n-1)$  degrees of freedom.

X1.5.10 Since the term  $(t_{1-q,n-1}s/\sqrt{n})$  in Eq X1.16 is non-negative, the decision point  $L_a$  is equal to or smaller than the regulatory limit  $L_r$ .

X1.5.11 The decision rule using the decision point in Eq X1.16 is carried out as follows:

X1.5.11.1 If  $x < L_a$ , then reject  $H_o$  and conclude no exceedance over the regulatory limit.

X1.5.11.2 If  $x \geq L_a$ , then do not reject the null hypothesis  $H_o$  and conclude exceedance over the regulatory limit.

X1.5.12 *False Positive Error:*

X1.5.12.1 The corresponding false positive error under this presumption can be calculated as well. Under the alternative hypothesis, the true mean is postulated to be lower than the regulatory limit. Namely,  $H_a: u = L_r - \delta_4$ ,  $\delta_4 > 0$ . Thus, False positive decision error:

$$\begin{aligned} &= \text{probability of saying} \\ &\text{that the true mean concentration is not lower} \\ &\text{than the regulatory limit when it is so,} \end{aligned} \quad (\text{X1.17})$$

$$\begin{aligned} &= \text{probability that the data observe } (\bar{x} \geq L_a) \text{ in favor of the null} \\ &\text{hypothesis } H_o \text{ when the alternative hypothesis } H_a \text{ is the correct one,} \\ &= \text{Prob}(\bar{x} \geq L_a | H_a) \\ &= \text{Prob}\{Z \geq [L_a - (L_r - \delta_4)] / (\sigma/\sqrt{n})\}, \text{ and} \\ &= \text{Prob}\{Z \geq Z_{1-q} + \delta_4/(\sigma/\sqrt{n})\}, \delta_4 > 0, q < 0.5 \end{aligned}$$

X1.5.12.2 As can be seen in Eq X1.17, the false positive error is a function of how much the true mean,  $\mu$ , is lower than the regulatory limit  $L_r$ . This difference is  $\delta_4$  expressed in the unit of the standard error of the mean ( $\sigma/\sqrt{n}$ ), or altogether  $\delta_4/(\sigma/\sqrt{n})$ .

X1.5.12.3 False positive error rates for different values of  $\delta_4/(\sigma/\sqrt{n})$  are given in Table X1.2. When  $\delta_4$  approaches zero (thus,  $\delta_4/(\sigma/\sqrt{n}) \rightarrow 0$ ), the true value approaches the regulatory limit  $L_r$ . As the true value becomes smaller than  $L_r$  (when  $\delta_4/(\sigma/\sqrt{n}) > 0$ ), the false positive error becomes larger.

X1.5.12.4 It is to be noted that the false positive error is the exact complement of the chosen false negative error when the true value is at  $L_r$ ; there the two errors total 100 %.

**TABLE X1.2 False Positive Error ( $p$ ) Under Presumption Number 2**

NOTE 1—For Some Values of False Negative Error ( $q$ ), and True Values  $\delta_4/(\sigma \sqrt{n})$ .<sup>A</sup>

False Negative Error, $q$	If True Value As Number of Standard Errors Away from Regulatory Limit, or $\delta_4/(\sigma/\sqrt{n})$ , Is	False Positive Error, $p$
0.05	0	0.95
	1	0.74
	2	0.36
	3	0.09
0.10	0	0.90
	1	0.61
	2	0.24
	3	0.04
0.20	0	0.80
	1	0.44
	2	0.12
	3	0.02

<sup>A</sup> Where the true value = regulatory limit when  $\delta_4/(\sigma \sqrt{n}) = 0$ .

X1.5.12.5 When the population standard deviation,  $\sigma$ , is replaced by sample standard deviation,  $s$ , in Eq X1.17, the  $z$ -statistic is replaced by the  $t$ -statistic. The calculation of the false positive error now involves a non-centrality parameter and a statistician should be consulted.

X1.5.13 *Equivalency Between Decision Point Approach and Test of Hypothesis Approach:*

X1.5.13.1 The decision rule using the decision point given in Eq X1.15 or Eq X1.16 can be made to be equivalent to one using the upper 100 (1- $p$ ) % confidence limit approach in a statistical test of hypothesis.

X1.5.13.2 Recall that the decision rule using a decision point is to conclude exceedance of the regulatory limit if  $x \geq L_a$ .

X1.5.13.3 But  $L_a = L_r - t_{1-q,n-1}s/\sqrt{n}$  from Eq X1.16. Thus,  $x \geq L_a$  becomes  $x \geq L_r - t_{1-q,n-1}s/\sqrt{n}$ .

X1.5.13.4 Rearranging, we can conclude exceedance of the regulatory limit (using confidence limit approach) if:

$$\bar{x} + t_{1-q,n-1}s/\sqrt{n} \geq L_r \quad (\text{X1.18})$$

X1.5.13.5 Note that the left-hand side of Eq X1.18 is the upper 100 (1- $q$ ) % confidence limit in a statistical test of hypothesis. Thus, the decision point approach from Eq X1.16 and the hypothesis test approach from Eq X1.18 are equivalent in decision-making.

X1.5.13.6 The decision rule using the upper confidence limit in Eq X1.18 is carried out as follows:

(1) If  $(x + t_{1-q,n-1}s/\sqrt{n}) < L_r$ , then reject  $H_o$  and conclude no exceedance over the regulatory limit.

(2) If  $(x + t_{1-q,n-1}s/\sqrt{n}) \geq L_r$ , do not reject the null hypothesis  $H_o$  and conclude exceedance over the regulatory limit.

X1.6 *Decision Point Derivation Under Third Presumption*—The true (population) mean concentration is

presumed to be neither higher nor lower than the regulatory limit.

X1.6.1 The steps in deriving a decision point under this presumption are given in Fig. 1 (middle part of figure).

X1.6.2 Recall that the decision point derived from the first presumption is Eq X1.7, and that the decision point derived from the second presumption is Eq X1.16.

X1.6.3 Eq X1.7 leads to a decision point higher than the regulatory limit and Eq X1.16 leads to one lower than the regulatory limit. Since the third presumption is a neutral one, it seems reasonable to have a corresponding decision point which is neither higher nor lower than the regulatory limit. This is achieved by setting the decision errors  $p$  and  $q$  equal to each other at 0.50 (or 50 %). When  $p = q = 0.50$ ,  $t_{1-p,n-1} = t_{1-q,n-1} = 0$  and the two equations above become identical and are reduced to Eq X1.19:

$$L_a = L_r \quad (\text{X1.19})$$

X1.6.4 This is the derived decision point based on practical considerations under the third presumption.

X1.6.5 The decision rule using the decision point in Eq X1.19 is carried out as follows:

X1.6.5.1 If  $x < L_a$ , then conclude no exceedance over the regulatory limit.

X1.6.5.2 If  $x \geq L_a$ , then conclude exceedance over the regulatory limit.

X1.6.6 The confidence limit approach under this presumption is identical to Eq X1.19, since the confidence limits in Eq X1.9 and Eq X1.18 are similarly reduced to Eq X1.19, when:

$$p = q = 0.50.$$

X1.6.7 The false positive and false negative errors, when  $L_a = L_r$ , are:


False positive error:

$$\begin{aligned} &= \text{Prob}(\bar{x} \geq L_a \mid u < L_r), \\ &= \text{Prob}(\bar{x} \geq L_r \mid u < L_r), \\ &= \text{Prob}(Z \geq \delta_5/(\sigma/\sqrt{n})), \text{ where } u = L_r - \delta_5, \delta_5 > 0 \\ &< \text{Prob}(Z \geq 0), \text{ and} \\ &= 0.5. \end{aligned} \quad (\text{X1.20})$$

False negative error:

$$\begin{aligned} &= \text{Prob}(\bar{x} < L_a \mid u \geq L_r), \\ &= \text{Prob}(\bar{x} < L_r \mid u \geq L_r), \\ &= \text{Prob}(Z < \delta_6/(\sigma/\sqrt{n})), \text{ where } u = L_r - \delta_6, \delta_6 \geq 0, \\ &\leq \text{Prob}(Z < 0), \text{ and} \\ &= 0.5. \end{aligned} \quad (\text{X1.21})$$

When  $\delta_5$  and  $\delta_6$  are relatively small, the false positive and false negative errors will be approximately equal at 0.5 each. When  $\delta_5$  and  $\delta_6$  are not small, the errors will deviate from 0.5 substantially, depending on where the true mean  $u$  is. When the true mean is exactly at the regulatory limit,  $L_r$ , then  $\delta_5 = \delta_6 = 0$ , and the two errors are equal at 0.5.

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