

**VALIDATION CRITERIA**

**Comparability** is the acceptability of a new or modified analytical method as a substitute for an established method in the NSSP. To be acceptable the new or modified method must not produce a significant difference in results when compared to the officially recognized method. Comparability must be demonstrated for each substrate or tissue type of interest by season and geographic area if applicable.

**Comparison of Methods:**

New or modified methods demonstrating comparability to officially recognized methods must not produce significantly different results when compared

**Procedure to compare the new or modified method to the officially recognized method:** This procedure is applicable for use with either growing waters or shellfish tissue. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take two (2) aliquots and analyze one by the officially recognized method and the other by the alternative method. Actual samples are preferable; but, in cases where the occurrence of the analyte/measurand/organism of interest is intermittent (such as marine biotoxins), spiked samples can be used. Samples having a variety of concentrations which span the range of the method's intended application should be used in the comparison. Analyze a minimum of thirty (30) paired samples for each season from a variety of growing areas for a total of at least 120 samples over the period of a year for naturally incurred samples. For spiked samples analyze a minimum of ten (10) samples for each season from a variety of growing areas for a total of at least 40 samples over the period of a year.

**Data:**

Sample type \_\_\_\_\_

Date	Sample/Station #	Conc. Recognized method	Conc. Alternative Method
	1		
	2		
	3		
	4		
	5		
	6		
	7		
	8		
	9		
	10		
	n		

n is the last sample in the comparison

**For shellfish samples, repeat for each tissue type of interest**

**Data handling to compare the new or modified method to the officially recognized**

Two methods of analysis are considered to be comparable when no significant difference can be demonstrated in their results. To determine whether comparability in methods exists, a two-sided t-test at a significance level ( $\alpha$ ) of .05 will be used to test the data. Either a paired t-test or Welch's t-test will be used depending upon the shape of the distributions produced by the data for each method and their respective variances. Use log transformed data for the results obtained from microbiological methods. The appropriate t-test to be used for the analysis is determined in the following manner.

1. Test the symmetry for the distribution of results from both the officially recognized analytical method and the proposed alternative analytical method.
2. Calculate the variance of the data for both the officially recognized analytical method and the proposed alternative analytical method.
3. Values for the test of symmetry for either method outside the range of -2 to +2 indicate a significant degree of skewness in the distribution.

4. A ratio of the larger of the variances of either method to the smaller of the variances of either method  $>2$  indicates a lack of homogeneity of variance.
5. Use either the paired t-test or Welch's t-test for the analysis of the data based on the following considerations.
  - If the distribution of the data from the officially recognized analytical method and the proposed alternative analytical method are symmetric (within the range of -2 to +2) and there is homogeneity of variance use a paired t-test for the data analysis.
  - If the distributions of the data for both analytical methods are symmetric (within the range -2 to +2) but there is a lack of homogeneity of variance in the data, use Welch's t-test for the analysis of the data.
  - If the distributions of the data from the officially recognized and proposed alternative analytical methods are skewed (outside the range -2 to +2) and the skewness for both methods is either positive for both or negative for both and there is homogeneity of variance in the data, use the paired t-test for the analysis of the data.
  - If the distributions of the data from the officially recognized and the proposed alternative analytical methods are skewed and the skewness for both analytical methods is either positive or negative for both but the data lacks homogeneity of variance, use Welch's t-test to analyze the data.

**Data summary for the comparison of the new or modified method to the officially recognized method:**

Value for the test of symmetry for the distribution of the data generated by the officially recognized method \_\_\_\_\_

Value for the test of symmetry for the distribution of the data generated by the proposed alternative method \_\_\_\_\_

Variance of the data generated from the officially recognized analytical method \_\_\_\_\_

Variance of the data generated from the proposed alternative analytical method \_\_\_\_\_

Ratio of the larger to the smaller of the variances generated by the officially recognized and proposed analytical methods \_\_\_\_\_

Is there a significant difference between the analytical methods Y/N