Chapter 832

Tolerance Intervals for Exponential Data

Introduction

This routine calculates the sample size needed to obtain a specified coverage of a β-content tolerance limit at a stated confidence level for data from the exponential distribution. These intervals are constructed so that they contain at least 100β% of the population with probability of at least 100(1 - α)%. For example, in water management, a drinking water standard might be that one is 95% confident that certain chemical concentrations are not exceeded more than 3% of the time.

Difference Between a Confidence Interval and a Tolerance Interval

It is easy to get confused about the difference between a *confidence interval* and a *tolerance interval*. Just remember than a *confidence interval* is a probability statement about the value of a distributional parameter such as the mean or proportion. On the other hand, a *tolerance interval* is a probability statement about a proportion of the distribution from which the sample is drawn.

Technical Details

The exponential distribution is often used for length of life data. The exponential density function is

$$f(x;\theta) = \frac{1}{\theta}\exp(-x/\theta), \quad x > 0, \theta > 0.$$

This section uses the results given in Guenther (1977). A tolerance limit is constructed from a random sample so that a specified proportion of the population is contained either above or below the limit. The limit is of the form

$$L_1 = k\bar{x}$$

where $\bar{x}$ is the sample mean and *k* is calculated as described below.

Proportion of the Population Covered

An important concept is that of *coverage*. Coverage is the proportion of the population distribution that is above or below the limit.

Solving for N

Let N be the sample size, P the proportion of the population covered, $(1 - \alpha)$ the confidence level, δ the proportion exceedance margin, and α' the probability that the coverage is greater than $P + \delta$. Guenther (1977) shows that the minimum value of N for a **lower, one-sided tolerance limit** is the smallest value of N that satisfies

$$\frac{\chi^2_{2N;1-\alpha}}{\chi^2_{2N;\alpha'}} \leq \frac{\chi^2_{2;1-P}}{\chi^2_{2;1-P-\delta}}$$

The value of k is given by

$$k = \frac{N\chi^2_{2;1-P}}{\chi^2_{2N;1-\alpha}}.$$

Guenther (1977) also shows that the minimum value of N for an **upper, one-sided tolerance limit** is the smallest value of N that satisfies

$$\frac{\chi^2_{2N;\alpha}}{\chi^2_{2N;1-\alpha'}} \geq \frac{\chi^2_{2;P}}{\chi^2_{2;P+\delta}}$$

The value of k is given by

$$k = \frac{N\chi^2_{2;P}}{\chi^2_{2N;\alpha}}.$$

where $\chi^2_{df;p}$ is the p^{th} quantile of a chi-square distribution with df degrees of freedom.

Example 1 – Calculating Sample Size

Suppose a study is planned to determine the sample size required to compute a lower 95% tolerance limit that covers 90% of an exponential population. The researchers want to investigate using a δ of 0.01, 0.02, or 0.05 with an α′ of 0.05.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Sample Size**
Limit Type .... **Lower Tolerance Limit**
Proportion Covered (P) **0.9**
Confidence Level (1 – α)............................... **0.95**
Coverage Proportion Exceedance (δ)........... **0.01 0.025 0.05**
α' = Pr(p ≥ P + δ)... **0.05**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Reports

Numeric Results

Solve For: Sample Size N
Interval Type: Lower Tolerance Interval

		Proportion of Population Covered				
Confidence Level 1 - α	**Sample Size N**	**Value P**	**Exceedance Margin δ**	**Upper Limit P + δ**	**Pr(p ≥ P + δ) α'**	**Tolerance Factor k**
0.95	883	0.9	0.010	0.910	0.05	0.0998
0.95	120	0.9	0.025	0.925	0.05	0.0912
0.95	22	0.9	0.050	0.950	0.05	0.0767

1 - α Confidence Level. The proportion of studies with the same settings that produce tolerance intervals with a proportion covered of at least P.
N The number of subjects.
P The proportion of the population covered. It is the probability of being greater than the tolerance limit based on the exponential distribution.
δ Proportion Covered Exceedance Margin. The value that is added to P to set an upper bound on the coverage at P + δ.
P + δ The upper limit of the proportion covered, P. It is a measure of the precision (closeness) of the actual coverage to P.
p The value of P computed from a random sample.
α' The probability that the sample value p is greater than P + δ. It is set to a small value such as 0.05 or 0.01. α' = Pr(p ≥ P + δ).
k The tolerance factor used in calculating the tolerance interval from a sample. The sample tolerance limit is k (Mean).

Summary Statements

A single-group design will be used to obtain a one-sided 95% lower limit tolerance interval where the target proportion of the population covered is 0.9. The underlying data are assumed to follow an exponential distribution. To produce a lower limit tolerance interval where the probability that the coverage (0.9) is exceeded by more than 0.01 is 0.05, 883 subjects will be needed. The factor k for computing the tolerance limit is 0.0998.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	883	1104	221
20%	120	150	30
20%	22	28	6

Dropout Rate The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
N The evaluable sample size at which the tolerance interval is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated tolerance interval.
N' The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
D The expected number of dropouts. D = N' - N.

Dropout Summary Statements

Anticipating a 20% dropout rate, 1104 subjects should be enrolled to obtain a final sample size of 883 subjects.

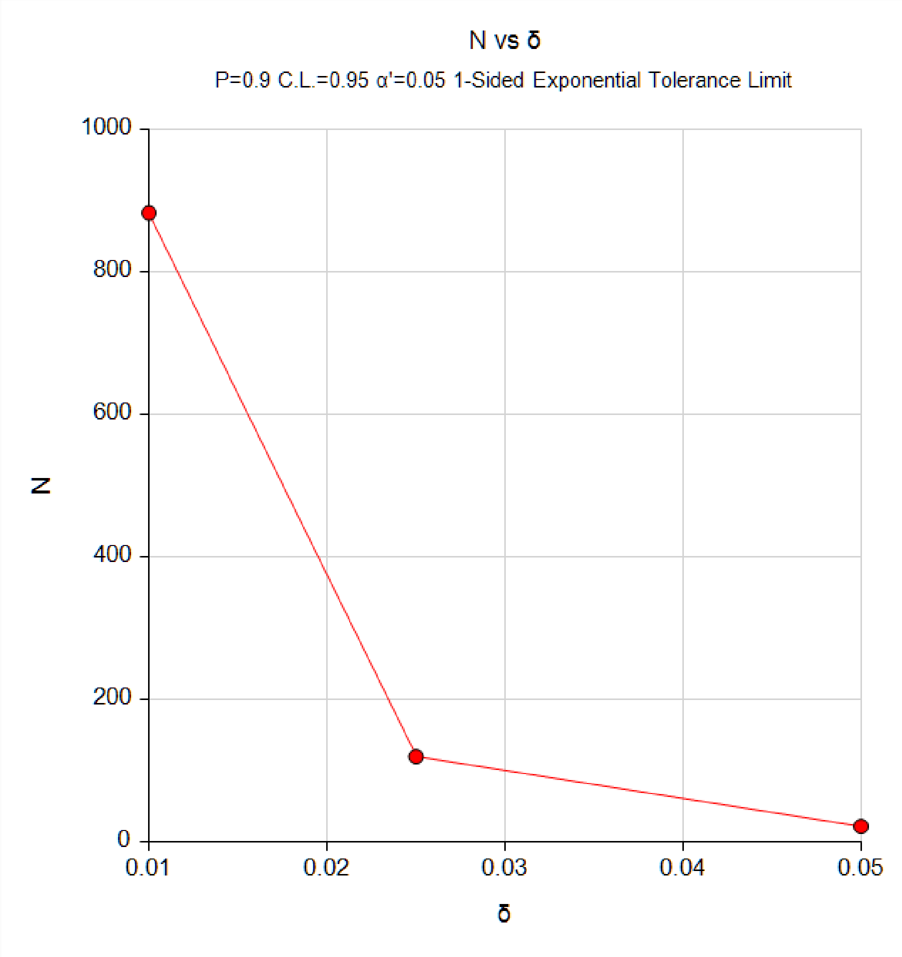
References

Faulkenberry, G.D. and Weeks, D.L. 1968. 'Sample Size Determination for Tolerance Limits.' Technometrics, Vol. 10, No. 2, Pages 343-348.
Guenther, William C. 1972. 'Tolerance Intervals for Univariate Distributions.' Naval Research Logistics Quarterly, Vol. 19, No. 2, Pages 309-333.
Guenther, William C. 1977. Sampling Inspection in Statistical Quality Control. Griffin’s Statistical Monographs, Number 37. London.
Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
Krishnamoorthy, K. and Mathew, T. 2009. Statistical Tolerance Regions. John Wiley, New York.

This report shows the calculated sample size for each of the scenarios.

Plots Section

Plots



This plot shows the sample size versus the three values of δ.

Example 2 – Calculating Sample Size

Continuing Example 1, the researchers want to show the impact of various sample sizes on α'. They decide to determine the value of α' for various value of *N* between 60 and 200, keeping the other values the same except that they set δ to 0.025.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **α' = Pr(p ≥ P + δ)**
Limit Type .... **Lower Tolerance Limit**
N (Sample Size).. **60 to 200 by 20**
Proportion Covered (P).................................. **0.9**
Confidence Level (1 – α)................................ **0.95**
Coverage Proportion Exceedance (δ)........... **0.025**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Reports

Numeric Results

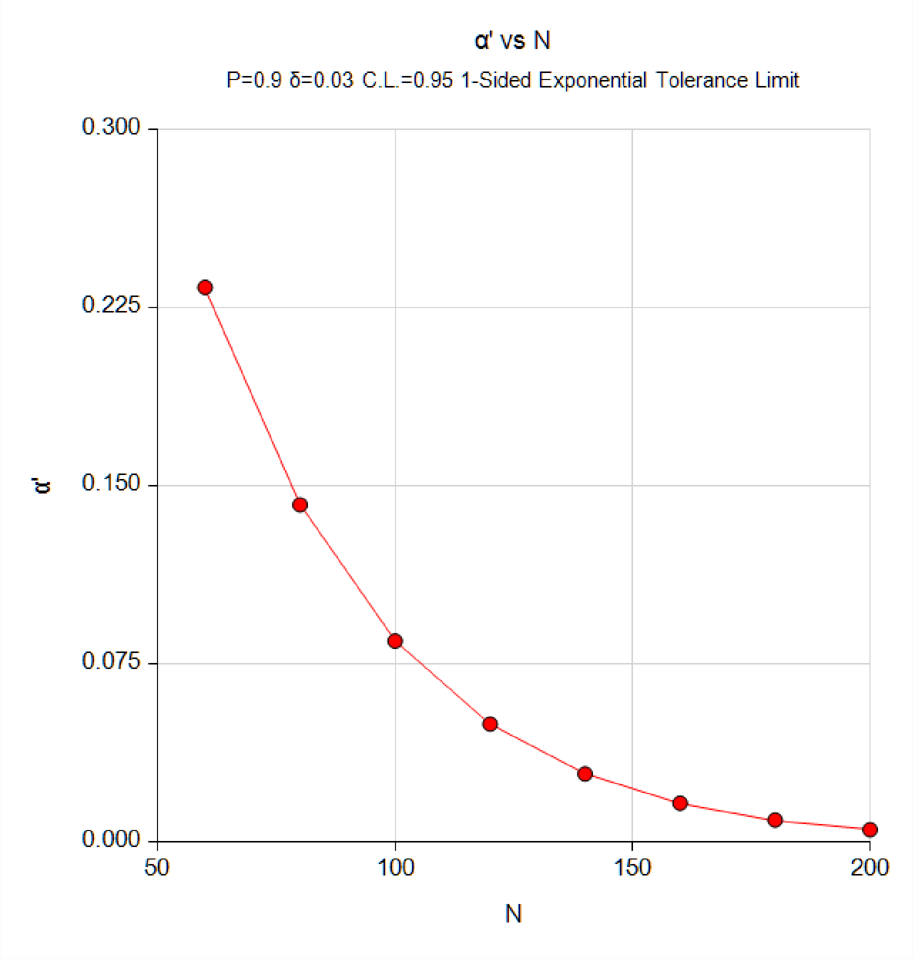
Solve For: α' = Pr(p ≥ P + δ)
Interval Type: Lower Tolerance Interval

		Proportion of Population Covered				
Confidence Level 1 - α	Sample Size N	Value P	Exceedance Margin δ	Upper Limit P + δ	Pr(p ≥ P + δ) α'	Tolerance Factor k
0.95	60	0.9	0.025	0.925	0.234	0.0863
0.95	80	0.9	0.025	0.925	0.142	0.0885
0.95	100	0.9	0.025	0.925	0.085	0.0901
0.95	120	0.9	0.025	0.925	0.050	0.0912
0.95	140	0.9	0.025	0.925	0.029	0.0922
0.95	160	0.9	0.025	0.925	0.016	0.0930
0.95	180	0.9	0.025	0.925	0.009	0.0936
0.95	200	0.9	0.025	0.925	0.005	0.0941

This report shows the impact on α' of various sample sizes. Since the value of the *Tolerance Factor k* is not related to α' or δ, this report allows you to calculate *k* for use with sample data.

Plots Section

Plots



This plot shows the sample size versus α'.

Example 3 – Validation using Guenther (1977)

Guenther (1977) page 181 gives an example in which P = 0.9, 1 – α = 0.95, $P + \delta$ = 0.95, and α′ = 0.05. He obtains a sample size of 22 and a k of 0.7664.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Sample Size**
Limit Type .... **Lower Tolerance Limit**
Proportion Covered (P) **0.8**
Confidence Level (1 – α)............................... **0.9**
Coverage Proportion Exceedance (δ)............ **0.15**
α' = Pr(p ≥ P + δ)... **0.05**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Solve For: Sample Size N
Interval Type: Lower Tolerance Interval

		Proportion of Population Covered				
Confidence Level 1 - α	Sample Size N	Value P	Exceedance Margin δ	Upper Limit P + δ	Pr(p ≥ P + δ) α'	Tolerance Factor k
0.95	22	0.9	0.05	0.95	0.05	0.0767

PASS also calculates the sample size to be 22. The value of k matches to within rounding.