Introduction

A frequent question posed to the RAC or posted on the RAC Forum relates to calculating the sample size “n” required in experimentation. Engineers use samples to estimate or test performance measures (PM) such as reliability, MTTF, etc. Having an adequate sample size is important, for it determines the amount of time and dollars dedicated to the effort.

The sample size used in an experiment depends, first, on the statistical distribution of the random variable (r.v.) in question (e.g., device life). Such life may be distributed Normally, a symmetric distribution whose standard deviation is usually smaller than its mean and hence induces a moderate variability. Therefore, a smaller sample size can still yield an acceptable level of certainty (or uncertainty) regarding estimates and tests.

If the r.v. life is distributed say Exponentially, a highly skewed distribution having a standard deviation as large as its mean, the situation differs. Large variances induce large variability. Hence, the r.v. can now attain either very small or very large values. This fact introduces higher levels of uncertainty in estimations, which have to be compensated by drawing larger sample sizes. Therefore, inherent variability, or variance of the r.v. under study, constitutes the second factor of importance in sample size determination.

Finally, we have the issue of the level of “confidence” in estimation problems or of the Types I and II errors\(^1\) in testing problems. To obtain higher confidence, all other factors being equal, we require wider “confidence intervals” (CI), which are usually not very useful. To reduce the width of a CI, we need to draw a larger sample. If instead of deriving a CI (estimation), we are testing, then we also need to consider the Type II error.

Summarizing, derivation of adequate sample sizes for testing or estimating a parameter requires three elements: the distribution of the r.v., its variability, and the risks of erring in the process of deriving such estimations or tests.

Sample Size for Interval Estimation of the Normal Mean

When a device life is distributed Normally, and we want to obtain an estimate of its MTTF, we base our sample size estimations on the formula for the CI for the mean \((\mu)\):

\[
\bar{x} \pm z_{\alpha/2} \frac{\sigma}{\sqrt{n}} = \bar{x} \pm H
\]

In its half-length \((H)\), which is the amount that is added and subtracted from the sample mean, the CI formula includes four elements. The four elements are, the confidence level \((1 - \alpha)\) desired, the random variation \((\sigma)\) in the Life of the device, the sample size \((n)\) required to fulfill the requirements and the Normal Standard percentile \((z_{\alpha/2})\).

The preceding probability statement says that the CI will cover the true MTTF at least 100\((1-\alpha)\) % of such times (e.g. 95% of the times). Let’s assume we know the standard deviation of the population. Consider now pre-establishing a fixed CI half-length of \(H=z_{\alpha/2} \times \sigma/\sqrt{n}\), about the true MTTF, for a pre-specified

\(^1\) We commit a Type I Error when we decide that the alternative hypothesis \((H_1)\) is true, when in fact the null \((H_0)\) is true (e.g. assume that the mean is \(\mu_1\), when in fact it is \(\mu_0\)).

We commit a Type II Error when we decide that the null hypothesis \((H_0)\) is true, when in fact the null \((H_0)\) is true (e.g. assume that the mean is \(\mu_0\), when in fact it is \(\mu_1\)).
Suppose now that the device Life has a Normal distribution, but the standard deviation $\sigma$ is unknown, or is unknown and estimated by $s$. Suppose that, instead of deriving a CI, we require the sample size $n$ for a hypothesis test. Then, in addition to Type I error $\alpha$, we must also consider Type II error $\beta$. Such error yields a difference of $\delta = \mu_0, \mu_1$.

The sample size is obtained by considering a system of two equations, derived from the Operating Characteristic function (5), and assuming the two error probabilities $\alpha$ and $\beta$ are given. Solving the resulting system of two equations yields the required sample size:

$$n = \left[\frac{(z_\alpha + z_\beta)\sigma}{\delta}\right]^2$$

In the previous example, assume we now want the sample size $n$ for a test that detects a difference of two units ($\delta = 2$) in MTTFs with errors $\alpha = 0.05$ and $\beta = 0.1$, when $\sigma = 8.6$:

$$n = \left[\frac{(z_{0.05} + z_{0.1})\sigma}{\delta}\right]^2 = \left[\frac{(1.65 + 1.28) \times 8.6}{2}\right]^2 = 158.7 \approx 158$$

By adding the extra requirement that we err if we accept a MTTF $\mu_1$ further than 2 units away from the true $\mu$, the sample size $n$ has increased to 158. Error $\beta$ can now be at most 10% yielding $z_\beta = z_{0.1} = 1.28$. We have discussed these derivations in the START on OC Functions (5). The interested reader will find more details and numerical examples in that reference.

### Sample Size for Interval Estimation of a Proportion

A frequent query submitted to RAC deals with determining the sample size required for estimating the true proportion defective “$p$,” or the true reliability “$R$” of a device, for a given Mission Time.

These two cases are, conceptually from a statistical point of view, handled the same. For, if we know the reliability required for a mission time “$T$,” or we can estimate it, then a device failure to meet such reliability requirement is equivalent to it being “defective.” Hence, the unreliability “$p$” is now P {Device Life $<$ $T$} = $p = 1 - R$ and, from the CI formula:

$$\bar{p} \pm z_{\alpha/2} \frac{p(1-p)}{n} = \bar{p} \pm H$$
If, as before, we pre-establish the “precision” H, and the “confidence” (1 - α) then, after some algebra, we obtain the formula for the sample size “n” required to fulfill these:

\[
z_{\alpha/2} \sqrt{\frac{p(1-p)}{n}} = H \Rightarrow n = \frac{z^2}{\alpha/2} \left( \frac{p(1-p)}{H^2} \right)
\]

To illustrate the percent defective (PD) calculations, assume we want to obtain the sample size required to estimate, with an 80% confidence (α = 0.2) the PD in a production lot. Assume a precision “H” of, at most, 3% (e.g. the maximum distance we want such estimate “p” to be from the true, but unknown, lot PD, either by excess or by defect). We say: H = 0.03, with confidence (1-α) = 0.8. We need, as with the Student t case, a preliminary estimate of the true lot PD parameter. We can obtain such estimate from a pilot survey or historical data (or, worst case, by assuming p = 0.5). Let, in our example, this estimate be p = 0.05. Then, the sample size required is:

\[
n = (z_{\alpha/2} / H)^2 \times p(1-p) = (1.28/0.03)^2 \times 0.05 \times 0.95 = 86.47 \approx 87
\]

Hence, a sample of n = 87 yields an estimate of PD “p”, such that 80% of the time, it is not further than 3% from the true but unknown PD. The procedure when nxp and nx(1-p) are greater than 5. Our example is borderline, since nxp = 87 × 0.05 = 4.35 < 5.

Assume we want instead an estimate of device reliability, for a Mission Time T, and we know it is somewhere around 0.95. If the reliability point estimate is: R = 1 - 0.5 = 0.95, then the probability of failure in time T is p = .05. Also assume a “precision” H = 0.03 (i.e. no further than 0.03 above or below 0.95) with at least 80% “confidence.” Then, we perform the same calculations above (p = 1 - R) obtaining the same sample size n = 87.

An alternative method consists of using Binomial nomographs, which can be found in the References 1, 5, 10, 11 or 12. Nomographs are very useful in determining sample sizes when, instead of a CI, we derive a hypothesis test. Then, in addition to Type I error α, we must also consider Type II error β, which comes from accepting a bad hypothesis.

**Sample Size for Estimating the Exponential Mean**

We know, from Reference (4), that if “n” devices have lives X_i, i = 1, … , n, distributed as Exponential with MTTF = μ, then the statistic 2T/μ (where T = Σ X_i) is distributed as Chi Square (X^2) with DF = 2n. From this we get the 100(1-α)% CI, say 95%, for MTTF (μ):

\[
\begin{align*}
\frac{2T}{X^2_{2n,1-\alpha/2}} &< \frac{\mu}{2} < \frac{2T}{X^2_{2n,\alpha/2}}; \text{or, } \frac{2T}{X^2_{\alpha/2,2n}} - \mu = \frac{2T}{\mu} - \frac{\mu}{1-\tau}.
\end{align*}
\]

Following Reference 1, we denote C = X^2_{2n,α/2} and D = X^2_{1-α,2n}. We solve the preceding system of two equations for variables C, D, and τ. After some algebra manipulations, we obtain:

\[
\tau = \frac{C - D}{C + D} \Rightarrow C = \frac{X^2_{2n,\alpha/2}}{D} = \frac{1 + \tau}{1 - \tau}.
\]

Therefore, to obtain the adequate DF, we only need to inspect the Chi Square Tables, finding the ratio that fulfills the conditions, for confidence (1-α) and precision τ. For example, assume we seek the sample size requirement for a 90% CI for the MTTF, with a precision of 45%. Then, 1-α = 0.9, α = 0.1, α/2 = 0.05, τ = 0.45 and ratio C/D is:

\[
C = \frac{X^2_{0.05,24}}{36.415} \approx 2.62 \approx 1 + 0.45 = 1.45 \approx 2.636; \quad D = \frac{X^2_{0.95,24}}{13.848} \approx 0.55.
\]

**Hence**: 2n = 24 ⇒ n = 12

When the sample size required is large (n>30), we can use the Normal approximation to the Chi Square distribution: \( z = \sqrt{2\chi^2_{n-1}} \approx \sqrt{2n - 1} \). With some algebra, we then obtain:

\[
\left( \frac{\sqrt{4n-1 + z_{\alpha/2}}}{\sqrt{4n-1 - z_{\alpha/2}}} \right)^2 = \frac{1 + \tau}{1 - \tau} \Rightarrow \frac{1}{4} + \left( \frac{1}{2} \right) z_{\alpha/2}^2 = \frac{1}{2} \left( \frac{1 + \sqrt{1 - 1/\tau^2}}{1 - \tau} - 1/2 \right)
\]

For example, assume we now seek the sample size requirement for a 90% CI for MTTF, with a precision of 20%. Then, 1-α = 0.9, α = 0.1, α/2 = 0.05, z(0.05) = 1.65, and τ = 0.2. The result is:

\[
n = \frac{1}{4} + \left( \frac{1}{2} \right) z_{0.05}^2 \left[ \frac{1}{0.2} + \sqrt{\frac{1}{0.2^2} - 1} \right] - \frac{1}{2} = 0.25 + \frac{1.65^2}{2} \left( \frac{5 + \sqrt{25 - 1}}{0.2} \right) - 0.5 = 64.4 \approx 65
\]

To verify this, we calculate the ratio of the two Chi Squares, with DF = 2n = 130 (for, 64.4 ≈ 65 ≈ 130/2):

\[
\frac{X^2_{0.95,130}}{X^2_{0.05,130}} = \frac{157.6}{104.7} = 1.499 \approx \frac{1 + \tau}{1 - \tau} = \frac{1 + 0.2}{1 - 0.2} = \frac{1.2}{0.8} = 1.5
\]
Hence, a 90% CI for the Exponential MTTF of the device lives, with a precision of 20% of the true MTTF, i.e. \( \tau = 0.2 \), would require drawing a sample of about 65 observations.

**Sample Size Requirements for Testing the Weibull Mean**

Sometimes we need the sample size requirements for testing, instead of for estimating parameters. We will illustrate this situation for the Weibull distribution. Assume we need the sample size “n” to test the Weibull Mean Life “m”, when shape parameter \( \beta \) is known, and Types I and II errors (producer and consumer risks), device reliability \( R \) and test time \( T \) are given. Weibull also involves a scale or characteristic life parameter \( \eta \) (now a “nuisance” parameter) that we, of necessity, need to substitute out of our equations.

We follow the algorithm described in (1). Using the Weibull density \( f(x) \), the cumulative distribution \( F(x) \), the mean life “m,” and the reliability \( R(x) \): 

\[
\begin{align*}
    f(x) &= \frac{\beta}{\eta^\beta} x^{\beta-1} \exp\left(-\left(\frac{x}{\eta}\right)^\beta\right) \quad \text{and} \quad F(x) = 1 - \exp\left(-\left(\frac{x}{\eta}\right)^\beta\right) \\
    \text{and} \quad m &= \eta \times \Gamma\left(\frac{1}{\beta} + 1\right) \\
    R(x) &= P\{X \geq x\} = \exp\left(-\left(\frac{x}{\eta}\right)^\beta\right)
\end{align*}
\]

We can construct a Test Plan \((n, c)\) that yields a sample size “n” and a critical number “c” (maximum failures to be observed) that fulfills the error and mission time problem requirements.

To achieve this, we assume that the r.v. “number of failures in test time \( T \),” denoted “x” can be approximated by a Binomial \((n, p)\) distribution. The parameters are “n,” the number of trials or devices placed on test, and “p,” the probability of having a device failure at any trial:

\[
p = F(T) = 1 - R(T) = 1 - \exp\left(-\left(\frac{T}{\eta}\right)^\beta\right)
\]

We define a hypothesis test for device mean life “m”, that fulfills Types I and II errors \( \alpha \) and \( \beta \), yielding Confidence \((1-\alpha)\) and Power \((1-\beta')\). The two hypotheses \( H_0: m = m_i \), for \( i = 0,1 \) were originally based on the Weibull mean. However, they are now converted, after some algebra, into hypotheses \( H_1^*: p = p_i \), for \( i = 0,1 \), based on Binomial parameter “p”:

\[
p_i = 1 - \exp\left(-\left(\frac{T}{m_i}\right)^\beta \times \left(\frac{1}{\beta} + 1\right)\right) ; i = 0,1
\]

Since shape \( \beta \) is known, reliability \( R(T) = 1 - p \) is only a function of \( T/m \), the known test time “T” and the hypothesized Weibull mean “m.” We can then establish a system of two Binomial equations that fulfill the required Types I and II errors (or risks) of the problem:

\[
\sum_{x=0}^{c} C^n_x p_0^n (1-p_0)^{n-x} = 1-\alpha; \text{and} \quad \sum_{x=0}^{c} C^n_x p_1^n (1-p_1)^{n-x} = \beta^*
\]

Solving this system of two equations, we obtain the appropriate values of “c” and “n” for the problem. This is the least preferred method, given its computational difficulties and trial-and-error approach to obtaining simultaneously “n” and “c”. We still use it (once “n” and “c” are obtained by one of the other two methods described below) but only to check their accuracy.

The alternative includes implementing a graphical method for obtaining such “n” and “c” values. It is similar to the method for obtaining an acceptance plan from an OC curve (5). Let’s explain its use through a numerical example.

Say we seek the sample size “n” required to test that the mean “m” of a Weibull life is 5000 hours, versus that is 1000 hours. The time \( T \) available for testing each device is only 500 hours, and both risks \( \alpha \) and \( \beta' \) are 0.01. The Weibull shape parameter is known to be \( \beta = 2 \). We first need to calculate the two \( p_i \), for \( i = 0,1 \), from the equations given above:

\[
p_0 = 1 - \exp\left(-\left(\frac{T}{m_0}\right)^\beta \times \left(\frac{1}{\beta} + 1\right)\right)
\]

\[
= 1 - \exp\left(-\left(\frac{500}{5000}\right)^2 \times \left(\frac{1}{2} + 1\right)^2\right) = 1 - 0.9922
\]

\[
p_1 = 1 - \exp\left(-\left(\frac{T}{m_1}\right)^\beta \times \left(\frac{1}{\beta} + 1\right)\right)
\]

\[
= 1 - \exp\left(-\left(\frac{500}{1000}\right)^2 \times \left(\frac{1}{2} + 1\right)^2\right) = 1 - 0.8217
\]

Then, we place the two \( p_i \) values obtained on the left scale of the Acceptance Plan Nomograph (Ref. 1, 5, 7). Probabilities for Confidence \((1-\alpha) = 1 - 0.01 = 0.99\) and Type II Error \( \beta' = 0.01 \) are placed on the right hand scale of Acceptance Plan Nomograph.

Finally, we draw two connecting lines for these pairs of points, \((p_0,1-\alpha)\) and \((p_1,\beta')\), obtaining values \( n = 46 \) and \( c = 2 \) in the chart margins. These values are obtained by projecting the intersection point of these two lines, in the margin scales.

We can then check the resulting \( n \) and \( c \) values, by substituting them, jointly with the values \( p_i \), for \( i = 0,1 \) and \( \alpha \) and \( \beta' \), in the above Binomial equations. That is:
\begin{equation*}
\sum_{x=0}^{c} C^n_x p_0^x (1-p_0)^{n-x} = 1 - \alpha = 0.99;
\end{equation*}
\begin{equation*}
\sum_{x=0}^{c} C^n_x p_1^x (1-p_1)^{n-x} = \beta' = 0.01
\end{equation*}

There exists however, a third alternative or method for this problem, consisting in certain approximations that allow us to avoid the above graphical procedures. When the sample size is large, say \( n > 20 \), the r.v. Number of Failures approximates the Normal, with \( \mu = np \) and \( \sigma^2 = np(1-p) \). We can then, using the same two hypothesized \( p_i \), for \( i = 0, 1 \), and the two errors or risks \( \alpha \) and \( \beta' \) given above, establish a system of two simultaneous equations to find adequate values for both \( n \) and \( c \):
\begin{align*}
\frac{c - np_0}{\sqrt{np_0(1-p_0)}} &= z_\alpha; \\
\frac{c - np_1}{\sqrt{np_1(1-p_1)}} &= -z_{\beta'}.
\end{align*}

Here, the \( z_\alpha \) are the Normal Standard percentiles for probability \( \alpha \). Solving this system for \( n \) and \( c \), we obtain the equations to find adequate values for both \( n \) and \( c \):
\begin{equation*}
n = \left[ \frac{z_\alpha \sqrt{p_0(1-p_0)} + z_{\beta'} \sqrt{p_1(1-p_1)}}{p_1 - p_0} \right]^2
\end{equation*}

and
\begin{equation*}
c = np_0 + z_\alpha \sqrt{np_0(1-p_0)}
\end{equation*}

For the same numerical example given before, and substituting proportions \( p_0 = 0.0078 \) and \( p_1 = 0.1783 \) in the above equations, we obtain the adequate values \( n \) and \( c \):
\begin{align*}
n &= \left[ 0.01 \sqrt{p_0(1-p_0)} + 0.01 \sqrt{p_1(1-p_1)} \right]^2 \\
&= 0.01 \left( \sqrt{p_0(1-p_0)} + \sqrt{p_1(1-p_1)} \right)^2 \\
&= 0.01 \left( \frac{p_1 - p_0}{2} \right)^2 \\
&= 2.326^2 \left( \frac{0.0078(1-0.0078) + 0.1783(1-0.1783)}{0.1783 - 0.0078} \right)^2 \\
&= 41.3 \approx 42
\end{align*}
\begin{align*}
c &= np_0 + z_\alpha \sqrt{np_0(1-p_0)} \\
&= 42 \times 0.0078 + 2.326 \times 0.0078 \times (1-0.0078) \approx 2
\end{align*}

We can verify how the three pairs of values \((n, c)\), obtained by these three alternative methods, are very close, as expected.

**Sample Size and Nonparametric Estimation for Zero Failures**

In the previous section, we discussed the case where we assumed that the device life is Weibull. Sometimes, we cannot (or do not want to) assume a specific distribution. In such cases, we must use a nonparametric approach (also known as distribution free, since no distribution is specified). However, there is a cost of not specifying a distribution: we now have to define the test length as equal to the Mission Time (not less, as we did above).

We again place “n” random, identically distributed, and independent items on a life test, now for the pre-specified Mission Time length “T.” Each item will either fail or pass the test of length T. Hence, each item on test is an independent Bernoulli trial and the r.v. number of observed failures “x”, out of “n” trials, is distributed Binomial. The failure probability is \( p = 1 - R \), where \( R \) is the probability that any item survives mission time T. Using the Binomial tables and the required reliability \( R \), we calculate the sample size “n” that provides the “Confidence” \((1 - \alpha)\) required in the problem statement.

For example, to demonstrate a reliability \( R = 0.95 \), with a Confidence \( 1 - \alpha = 0.9 \), for a Mission Time of T hours and no failures, we place “n” devices on a test of length T. Each device can fail the test with probability \( p = 1 - R = 0.05 \). Since zero failures implies that all “n” devices “survive”, we search the Binomial tables for a convenient sample size “n.” This “n” must yield zero failures \((c = 0)\), or equivalently twenty survivals, with Confidence \( 1 - \alpha = 0.9 \). The Binomial \((n, p)\) equation is then:
\begin{equation*}
\Pr \{ \text{Obtaining} \ "c" \ \text{or less Failures} \} = \sum_{x=0}^{c} C^n_x p^x (1-p)^{n-x}
\end{equation*}

Since the required Confidence \( 1 - \alpha = 0.9 \) and zero failures is \( c = 0 \), we have:
\begin{align*}
P \{ \text{Observing NO failures} \} &= (1-p)^n = R^n = 0.95^n = \alpha = 0.1 \\
\Rightarrow (0.95)^{45} = 0.0994 \approx 0.1, \ \text{for} \ n \approx 45.
\end{align*}

Hence, a sample of size \( n = 45 \) yields a confidence close to 0.9, of finding zero failures \((c=0)\) in a life test of Mission Time T, when the reliability for this mission time T is 0.95.

However, searching the Binomial \((n,p)\) tables for a suitable “n” can be a tedious and time consuming task. We can instead use an equivalent equation, derived from such Binomial probability for the Confidence, for the case of zero failures \((c=0)\) or twenty successes:
\[ \sum_{x=0}^{c} C_x p^x (1-p)^{n-x} = 1 - \text{Confidence} = \alpha \]

For \( c = 0 \) \[ \sum_{x=0}^{c} C_x p^x (1-p)^{n-x} = (1-p)^n \]

\[ = \exp(n \log(1-p)) = 1 - \text{Confidence} = \alpha \]

Taking Logarithms on both sides, noticing that \( p = 1 - R \), and after some algebra, we obtain:

\[ n = \frac{\log(1 - \text{Confidence})}{\log(1 - p)} = \frac{\log(\alpha)}{\log(R)} \]

For example, applying this formula to the immediately preceding example, we obtain:

\[ n = \frac{\log(0.1)}{\log(0.95)} = -1.0 \]

\[ -0.2227 = 44.89 \approx 45 \]

The results, obtained using the Binomial and the Logarithm formula, are close because both methods are totally equivalent. However, the second result (formula) is easier and faster to obtain than the first one (trial and error).

Summarizing, we first establish the problem requirements regarding the desired (1-\( \alpha \)) confidence and acceptable reliability \( R \). Then, we calculate the sample size \( n \) that satisfies these requirements. Such sample size \( n \) can then be used to estimate the reliability \( R \), with the desired confidence. The life test must be of length equal to Mission Time \( T \).

**Conclusions**

The theory for determining the sample size that meets a testing or estimation requirement is extensive and complex. Such theory is driven by the type of parameter we want to estimate or test, i.e., location, scale, or shape, and by the distribution of the sampling statistic we use to implement the hypothesis test or to obtain the estimation.

In this START Sheet, we have discussed the problem of estimating and testing some location parameters (mean, proportion) for the Normal, Exponential, and Weibull distributions, and for distribution-free (nonparametric) situations. Our objective has been to illustrate the logic and the statistical thinking behind the derivation of such sample sizes. A better understanding of this logic may help practicing engineers to better implement such procedures.

We have only discussed a few of the most widely used cases. There are many other situations of interest. For a more extensive and in-depth treatment of this subject, the reader is referred to Chapter 13, pages 699 to 776, of Reference 1.

An assessment of the complexity of these derivations may be provided by the fact that the referred Chapter 13 is the last one of this extensive, two-volume reliability handbook. However, the manifold advantages that deriving an adequate sample size for our problem provides in terms of savings in time and effort, far outweighs its theoretical complexities.

**Further Reading**


**About the Author**

Dr. Jorge Luis Romeu is the founder and director of the *Juarez Lincoln Marti International Education Project*, that provides books and faculty workshops to Iberoamerican institutions of higher education. JLM Project is the sponsor of the *QR&CI Project*. Romeu has over 30 years of statistics and operations research experience in consulting, research, and teaching.

As a consultant, Romeu has worked for both manufacturing and agriculture. He has worked in simulation modeling and data analysis, in software and hardware reliability, in software engineering, and ecological problems.

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For his work in education and research and for his publications and presentations, Romeu was elected Chartered Statistician Fellow of the Royal Statistical Society, Full Member of the Operations Research Society of America, and Fellow of the Institute of Statisticians. He has received several international awards, including five Fulbright and one Department of State Senior Specialist assignments to Mexico, Ecuador and the Dominican Republic. He has also held assignments in Spain and Venezuela, and is fluent in Spanish, English and French.

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