1. Select a test.
2. Select appropriate control materials.
3. Determine your TEA limits
   1. Select the TEA for the test; note the resources used for the selection.
   2. Select the Target Value (Clinical Decision Concentration) for each control; note the resource used for the selection.
   3. Calculate the TEA in units.
4. Determine current method performance
   1. Calculate the current method’s mean from a stable system for each control.
   2. Calculate the current method’s SD from a stable system for each control.
   3. Calculate the SEc and Sigma-metric for each control; if SEc is zero or a negative number, then your TE ≥ TEA. Stop reporting patient results immediately, verify your four Key Numbers of Quality, and fix the problem(s)
5. Select appropriate control rules
   1. Choose the appropriate Sigma-metrics QC Selection Tool for the number of controls used for the test.
   2. Locate the Sigma-metric value on the Sigma-scale (scale at the top of the X-axis).
   3. Validate the Sigma-metric against the SEc scale (scale at the bottom of the X-axis).
   4. Draw a vertical line from the Sigma-metric value to the SEc value.
   5. Assess probability of error rejection where the Sigma line intersects with the QC rule power curve.
   6. Identify candidate QC rules in which Ped is ≥ 0.90 (90%).
   7. Assess false rejection rates of candidate QC rules from the table [≤ 0.05 (5%)].
   8. Select the appropriate QC rule and total number of control measurements (N) that provide the lowest cost and are easiest to implement.
6. On-going monitoring of QC
   1. Create the QC chart.
   2. Determine how often a supervisor will review the QC chart, depending on the SEc or Sigma-metric.
   3. Initiate corrective action if SEc and Sigma are low.
   4. Develop a standardized process to investigate QC rule violations from daily, summary, and peer-reviewed QC data.
   5. Monitor the accuracy, precision, SEc, and Sigma at least on a monthly basis.
   6. Take corrective actions as needed; continue to target poorly-performing analytical systems.
7. Document this entire process.
8. Educate the analytical staff.
9. Communicate with upper management regarding the laboratory’s needs for a complete QC process.