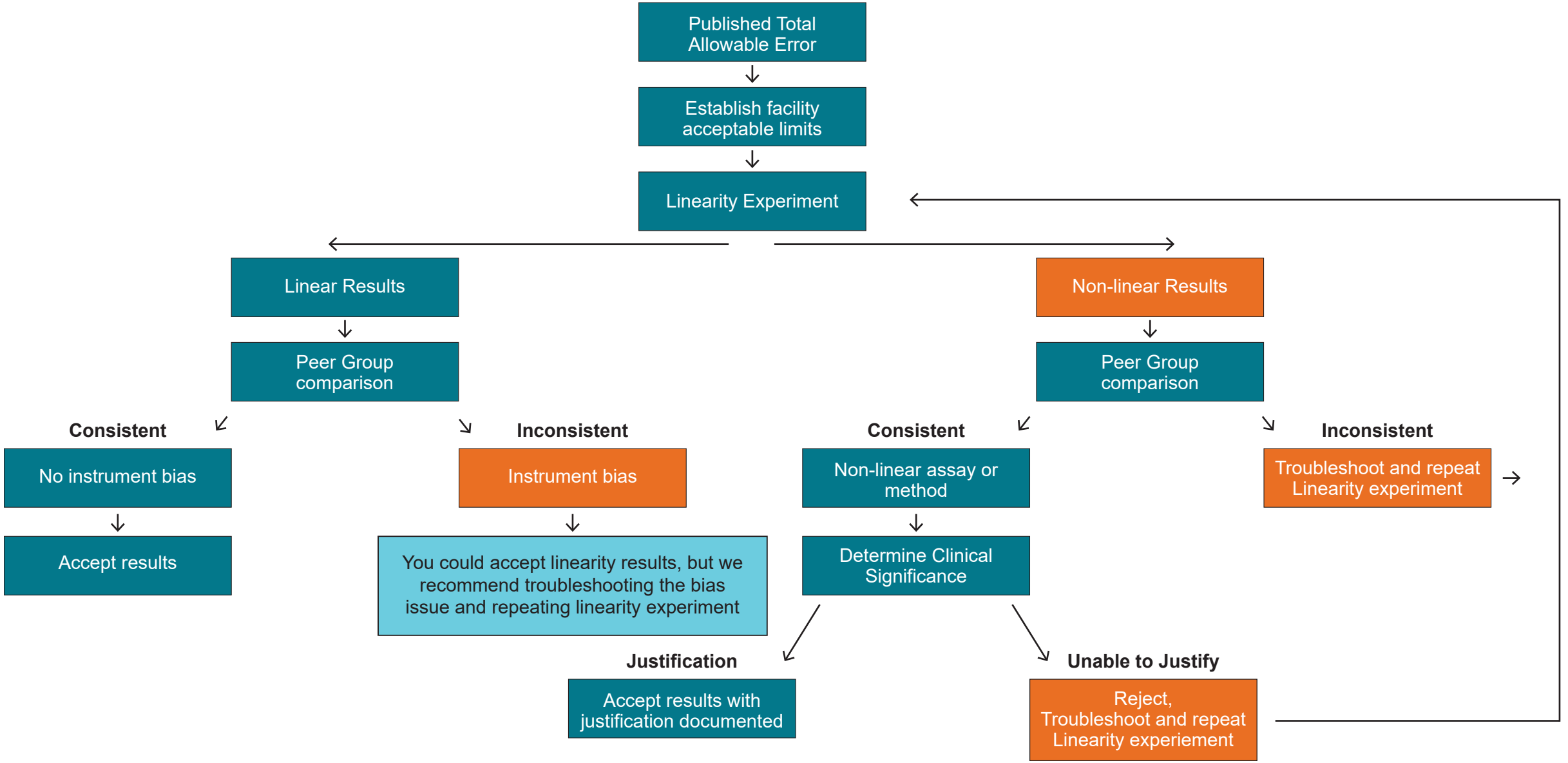
Published Total Allowable Error
Establish facility acceptable limits
Linearity Experiment
Linear Results
Peer Group comparison
Consistent
No instrument bias
Accept results
Inconsistent
Instrument bias
You could accept linearity results, but we recommend troubleshooting the bias issue and repeating linearity experiment
Non-linear Results
Peer Group comparison
Consistent
Non-linear assay or method
Determine Clinical Significance
Justification
Accept results with justification documented
Unable to Justify
Reject, Troubleshoot and repeat Linearity experiement
Inconsistent
Troubleshoot and repeat Linearity experiment