Supplier Selection:
When no previous quality and reliability records are available, or if sub tier supplier performance has been marginal, based on sub tier supplier ratings, the supplier shall conduct an onsite survey of the sub tier supplier (excluding distributors, material manufacturers, and build-to-print machine shops), which includes the sub tier supplier’s:
- capabilities
- facilities
- technical management program
Results of this survey and subsequent corrective action shall be documented, maintained, and retained as a quality record.

The supplier shall maintain rationale for their selection of sole source sub tier suppliers. The supplier shall consider cost effectiveness of qualifying multiple sources for critical components.

Supplier Evaluation: The supplier shall establish and maintain a system to schedule and conduct onsite supplier evaluations of sub tier suppliers (excluding distributors, material manufacturers, and build-to-print machine shops) to ensure compliance with procurement document requirements. The frequency, scope, and method for evaluating shall be based upon:
- criticality or complexity of items being procured
- known problems or difficulties
- documented risks
- quality history

The planned coverage of each evaluation shall be documented. In order to determine compliance with established requirements, coverage shall include examination of applicable:
- requirements,
- operations,
- parts,
- devices,
- materials,
- software,
- and documentation

The supplier shall document rationale for reductions in frequency or scope of evaluation. Results of evaluations, with recommendations for corrective action, shall be documented and retained as a quality record. Follow-up shall be performed to verify effective corrective action has been taken.