

Guidance 080 Reduced Testing Program

- a. A minimum of 3 consecutive lots tested by user site must be used for evaluation.
- b. If the user site results met the specifications for all lots and nothing else was observed that calls into question the reliability of the vendor's results, user site testing may be eliminated and materials received based on ID testing and vendor COA.
- c. If there was a confirmed failure of any lot tested by user site in the past year or the prior 3 lots fully tested (whichever is the higher number of lots), then the supplier cannot be deemed reliable. Verification that appropriate corrective actions have been taken by the vendor to address the failure must be performed. Testing by user site must be continued until at least 3 consecutive lots received meet user site specifications.
- d. No statistical comparison of user site results versus supplier results is necessary as long as the user site specification is the same as *or wider than the vendor specification*. If the user site specification is tighter or different than the vendor's specification, a statistical comparison of user site results and vendor results will be necessary.
- e. If sufficient data has been generated regarding the material and vendor under review (as outlined above), it is not necessary to have information whether or not the vendor performs skip lot testing in order to make a decision on the supplier's reliability.
- f. In rare instances, there may be regulatory commitments that indicate that user site will perform certain testing on incoming goods from vendors. If it is confirmed that a regulatory commitment was made:
 1. Evaluate if the effort (resources, variation fees, etc. required to make the regulatory change results in an overall benefit
 2. If the regulatory change has a significant benefit, initiate internal change control procedures to eliminate the test with supporting documentation justifying the change.
- iii. Once all requirements have been satisfied, reduce testing to COA review, ID testing and visual inspection unless additional testing is warranted for business purposes.
- iv. One (1) lot of the material must undergo full testing annually.
- v. For materials used for products intended for the EU market, it may be acceptable to perform ID testing from only one (1) container of each material receipt, provided that the requirements of Annex 8 are met and the assessment properly documented. As outlined in Annex 8, the