

ITEM	QUESTIONS	ANSWERS (for discussion)
Chapter 6 Production		
C 6.1	How much retention samples would be required?	<p>The manufacturer should determine sufficient quantities based on its product knowledge and testing required. Normally the retained samples should be sufficient to support at least two rounds of full testing requirements.</p> <p>(Reference Clause 7.14 – “Reference samples of materials and products shall be of a size sufficient to permit at least a full re-examination”)</p>
Appendix 2 Verification		
A 2.3	For existing (old) production equipment, is it acceptable to conduct Operational Qualification and Performance Qualification?	<p>For old(legacy) equipment, qualification should be performed when there are changes. If the equipment is moved from one location to another then Installation, Operation andPerformance Verification should also be performed.</p> <p>(Reference Clause 6.17 – “Significant changes to the facilities, equipment, testing and the processes which may affect the quality of the product shall be verified.”)</p> <p>(Reference Appendix 2, Clause 1.0 - “Re-verification shall be performed if there are significant changes to the facilities, systems, processes and equipment that may have impact on the quality of the finished products, and the changes would require regulatory approval. Where there are no significant changes, periodic review shall be performed to show that the facilities, systems, processes and equipment continue to meet the prescribed requirements.”)</p>