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Procedure no: INS/GCP/3/III-Rev 1

ANNEX III
TO PROCEDURE FOR CONDUCTING GCP INSPECTIONS
REQUESTED BY THE EMEA:
COMPUTER SYSTEMS

GCP Inspectors Working Group

Applies to: EMEA, EU/EEA Inspectorates	
Summary of scope: This procedure compiles the main aspects that are to be verified during the inspection of computer systems requested by the EMEA.	
Keywords: GCP Inspection, Computer systems	Public
Supersedes: version dated 20 September 2007 (updated in this Rev 1 version the reference to the PIC/S Guidance)	

Finalisation	Date
Adoption by GCP Inspectors Working Group	5 September 2007
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The EU GCP inspectors agreed to use as the reference for inspection of Computer Systems the published PIC/S Guidance on Good Practices for Computerised Systems in Regulated “GXP” Environments (PI 011-3). The hyperlink to the PIC/S site is <http://www.picscheme.org/index.php>

* Corrigendum due to an error in the wording in the Summary of scope (clinical laboratory replaced by computer systems)