

Procedure Review - Non-Deliverable Software Compliance to ASQR-7.5	Y	N	na	Comments
Is the scope of software control complete for all types?				
Executive (manufacturing machine operating system) controller software?				
PLC (programmable logic controller) software?				
In-house developed application software implementation process?				
COTS (Commercial Off-The-Shelf) application software?				
Part specific programs?				
Process specific recipes or parameter files)?				
Software Support Tools				
Are all manufacturing processes that use software covered in the procedure?				
Computer Numerical Control				
Numerical Control				
Distributed Numerical Control				
Gage Calibration				
Gage Tracking				
Statistical Process Control				
Coordinate Measuring Machine				
Robot Arm				
Sonic Inspection				
Heat Treat				
Dot Peen Marking				
Laser Marking				
Shot Peen				
Plasma Spray				
Computer Aided Design				
Computer Aided Manufacturing				
Post Processors				
Electrical Discharge Machining (laser/wire)				
Other...				
Organizational Responsibility 4.1.1				
Do procedures address organizational responsibility and authority including product and process integrity?				
Requirements Identification 4.1.2				
Do procedures explain/identify how requirements are documented?				
Is the software's purpose or function documented?				
Is the initiator (title/department) of the documented requirements identified?				
Is a specific form or document used for identifying requirements?				
Is the approver (title/department) of the documented requirements identified?				
Coding Standards 4.1.3				
Do procedures define coding standards?				
Are file naming conventions described? File names of both developmental and production versions?				
Is the unique software version/release defined?				
Are required program header information and comments defined?				
Is test library segregated from production library?				
Are programs named with a unique file name that enables the operator to distinguish if the code is approved for production?				
Verification and Validation 4.1.4				
Do procedures adequately address the verification and validation process?				
Is the Verification and Validation process defined?				
Is the test procedure or test description documented?				
Is the test procedure or test description reviewed?				
Is the test procedure or test description retained?				
What documentation will be retained that contains variable data as objective evidence showing the software performs its required function?				
Are 100% of the features tested traceable to requirements?				
Is software being reviewed and approved prior to use?				
For inspection software:				
Is approver someone acting in an acknowledged product integrity role?				
Is an independent method of validation required to provide an alternate set of results for correlation?				
Is there a requirement to conduct correlation study using an alternate method that shows program accuracy is within 10% of total product tolerance for programs used in inspection of parts?				

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Do procedures designate who will document the justification inspection programs can be approved, when the correlation shows program accuracy between 10% and 25%?				
Is greater than 25% considered unacceptable in ALL CASES?				
Target Environment 4.1.5				
Is the target environment identified adequately?				
Are interfaces to other software and computer hardware identified?				
Is the target computer hardware and software environment identified?				
Version Control 4.1.6				
Is there a process or tool that manages program version control?				
Is unique identification of each version of the software required?				
Does the software procedure require that each configuration item (that makes up a software product) be identified?				
Change Control 4.1.7				
Is the software change process defined adequately?				
Is there a process to identify problems using analysis for problem cause and implementation and verification of corrective action?				
Is re-verification and re-validation of software employed to ensure that the modified software meets the changed requirements?				
Access Control 4.1.8				
Are limited access controls defined in the procedure and in place?				
Do procedures define the read and write access of the master and copies?				
Do procedures require that manufacturing machine edit keys be controlled?				
Archiving Backup and Recovery 4.1.9				
Is the defined Archiving, Backup and Recovery process adequately documented?				
Is there a process to prevent/remove the use of obsolete software for production?				
Are master copies, duplicates and other copies being restricted and/or removed from all areas except the archive?				
Is obsolete software in the archive restricted to prevent unauthorized use?				
Are master copies being stored in a secure location?				
Does the software archival process allow for retrieval of all released software programs (for manufacturing traceability)?				
Identification Storage, Handling and Release 4.1.10				
Does the defined method for identification, storage, handling and release of software to the user include access to only the latest software program version?				
Training and Maintenance 4.1.11				
Are training and maintenance requirements defined?				
Documentation 4.1.12				
Is required documentation defined?				
Are the software development documentation requirements adequate?				
Are the software approval documentation requirements for software being released to production adequate?				
Supplier Oversight 4.1.13				
Is the defined process for supplier oversight adequate?				
How are software problems identified?				
How are software problems analyzed for cause?				
How are software problems corrected?				
How are software problems verified that corrective action is effective?				
COTS software acceptance 4.1.14				
Is the defined process for acceptance of purchased of vendor supplied software prior to use adequate?				
Analysis of Risks and Criticality 4.1.15				
Software Support Tool Development 4.1.16				
Is the process for Software Support Tool development adequate?				
Are the software requirements being documented in the program folder or equivalent?				
Is the design and code documented in the program folder or equivalent?				
Is the functional test of the software execution being documented in the program folder or equivalent?				
Is the software and documentation being controlled using internal configuration management procedures?				
Internal Audit 4.1.17				
Is the process for Software Internal audit adequate to ensure compliance to established software development, procurement and control procedures? Tool development adequate?				