Internal Audit Check list

Design

Created:	17/May 1995	Audit No 03	VM3/COP16 & 09 VOP 17
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Audit Date		Auditor	ISO 7.2 7.3

QUESTION: ~~For~~	RESPONSE:	Y/N
Check that the final design responsibility is a Sole Authority.	Top management	Y
Check that all products are C.E. marked and have a C.E. file.	Intrastats	Y
~~Verify that EMC testing has been identified where required.~~	CE Files	Y
Are the latest BS ISO MDD, CMDCAS requirements ~~are~~ available	Library, Paperport INTRASTATS	Y
Check that product classification is done to MDD, CMDCAS principles.	CE Files Intrastats	Y
Verify that each design was initiated from a job description & specification	Intrastats or QC22	
Has each design has received a job number and a job progress form	Intrastats or QC25	
Verify the existence of a design documentation checklist.	Intrastats or QC29	
Check that estimated times have been noted.		
Have final testing requirements, and test criteria, been identified		
Have concession notes have been raised on non-approved suppliers	Not normal	
Check that current status is identified on a regular basis.	Intrastat meetings	
Verify that design reviews are undertaken and that records are retained	Intrastat meetings	
Check that any amendments to design are logged	Intrastats or QC24	
Check that design output records are verified against design input		
Does design verification comply with COP 16 - 7.7.1 - .4		
Check that clinical trials have been carried out and relevant records retained	CE Files	
Verify that design validation has been carried out as required by form QC30		
Check that any design changes have been identified, recorded and approved		
Have risk analysis has been carried out and recorded at all relevant stages		
Check that CE files are complete, correct and maintained	Intrastats, Library	
Check and list current design files: Technical Library. Intrastats a) Red Plastic Holder BLUE - OX b) Red Binder &/or Red CE mark Binder VIVOO. c) Hardware R & D or Archives	RED Boxes	Y
Do all the files contain the master layout		Y
Are the sections in the master layout being filled in correctly		Y
Are the designated people filling in log sheets MOVING TO BEECHMORE		
Is information from the logs being copied to master files .	S. DRIVE + INTRASTATS	Y
Are design components kept separate from stock and adequately stored		
Are design component stocks labelled ~~and secured~~.		Y
~~Check the existance of design compliance forms~~		
~~Are these changes reviewed and approved~~		
~~Have risk analyses been carried out and recorded~~	CE Files	
Verify that all products have a C.E. file		Y
Check that these files are maintained JSC		Y
~~Verify that they are complete and correct~~		
If more space is required for answers use the reverse of this form		

LATEST PROJECTS ONLY

LATEST Projects only

* Add Vidmar Products