

Audit Checklist

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Audit Details					
Audit Number		Audit Transport of Blood Components to External Source Examination Audit (Blood Transfusion)			
Audit Scheduled Start		Audit Category Audit\Internal Audit\Examination Audit			
Checklist					
Title	Description	Completed By	Completed Date		
Examination Audit Checklist	Generic template for examination audit Instructions: Observe an operator undertake a specific laboratory process. The audit should take into account the process being observed, the operators ability to undertake it and the documentation associated with it. In all instances the evidence used to determine compliance must be listed in the audit checklist. Responses and evidence should be sufficiently detailed to recreate the audit if necessary. Where documents are used as evidence please list document numbers. Where dates are stated they should take the format dd/mm/yy.				
Questions					
Number	Question Text	Guidance	Response	Raise NC? (Y/N)	Raise Observation? (Y/N)
1	Laboratory process				
2	What process is being examined?	Processes may include but not exclusive to; Sample Collection and Handling, Sample Transport, Sample Reception, Referral to External Laboratories, Examination Procedures, Assuring the Quality of Examinations, Reporting results, Telephoned report, Amended report			

3	Is the environment and equipment suitable for undertaking the process?	Consider space, layout, lighting, noise, clutter, dust, equipment verification, maintenance, servicing			
4	Documentation				
5	Is there a procedure for the process being examined?	This may take the form of SOPs, Manufacturer's instructions, in-house instructions, policies, internal and external guidance, and associated templates. List all documents referred to in the audit response field.			
6	Is the procedure available at point of use?	State how the information was presented e.g. paper copy at point of use or electronic copy via PC.			
7	How was the procedure presented?	Electronic versions held on Q-Pulse/ QMS are the preferred method of retrieving required documentation, however paper copies/extracts are permitted in line with document control procedures.			
8	If paper copies / bench extracts etc are available, are they clearly defined on the Q-Pulse document record?	All extracts should be listed on the document distribution list as paper copies and under control as defined in the Document Control Procedure. Any extract or paper copy of the procedure not listed results in a document control failure.			
9	Are there active Risk and COSHH Assessments available for the process?	COSHH and RAs should be located on Q-Pulse/QMS. MSDS sheets where available will be on FTP or SHE. State document numbers if available			
10	Operator compliance with procedure				
11	Did the operator follow the prescribed procedure to undertake the process being examined?	Adherence to procedures is paramount to ensure staff safety and result reliability. If any part of the procedure is not followed a non-conformance must be raised			
12	Were there any issues in undertaking the procedure that would impact on the audit being carried out?	Document any equipment failures etc that would prevent the full examination audit being completed.			
13	If issues occurred whilst undertaking the procedure, did the operator follow the correct processes to resolve or escalate?	All operators should conform to non-conformance reporting procedures. If no failures were identified, the operator may be questioned to demonstrate this compliance			

14	Was the resulting outcome within expected parameters following resolution actions?	Consider notification to the user if results of examination process impact on diagnostic result.			
15	Operator understanding of the Procedure				
16	Has the operator completed relevant training for the procedure being examined?	State what training and competence records are available and which have been completed and signed off.			
17	Does the operator have evidence of competency assessment?	Following initial training, periodic competency assessments are required within a one to three year period dependant on level of risk presented by process			
18	Was the operator aware of any limitations to the procedure?	Describe any interferences e.g. haemolysis, delay in transportation, rejection criteria			
19	For the examination in question, is the method in control?	Allow the auditee to describe the IQC and calibration procedure for this assay or any quality assurance procedure in place			