



Record-Reliability Controls

(Ref. SOP VAL 060)

Description / Title of the Record being assessed:	Impact Rating (D, I, N):
Description of the Inventory Item(s) which generates this record:	Equipment No:
Brief description of the role / use of the Record:	

Master Copy for Storage:	Paper <input type="checkbox"/>	Electronic <input type="checkbox"/>	Both (Hybrid) <input type="checkbox"/>	!
Record is Approved:	On Paper <input type="checkbox"/>	Electronically <input type="checkbox"/>	On Both (Hybrid) <input type="checkbox"/>	Not Required <input type="checkbox"/>

Generic Control Measures		Reliability-attribute supported by Control				Minimum Reference Standard	Assessment - Commentary
		Accurate	Authentic	Available	Integral		
Infrastructure Protection	Physical security					Indirect	
	Environmental controls					Indirect	
	"Malware" protection					Indirect	
Security Management	Access control					No-Impact	
	Password management					Indirect	
	Authorisation process					Indirect	
	External-access checks					Indirect	
	Centralised storage					Indirect	
	User function profiles					Direct	
	User access profiles					Direct	
	Unique accounts					Direct	
	Breach response					Direct	
	Backup and Restore	Back-up procedure					No-Impact
Checking of outcome						No-Impact	
Redundant copies						Indirect	
Remote storage						Direct	
Automated process						Direct	
High-availability system						Direct	
Disaster Recovery	Response capability					No-Impact	
	Agreed plan / goal					Indirect	
	Tested process					Indirect	
Validation and Change Control	Specification					No-Impact	
	Authorisation process					No-Impact	
	Implementation Testing					No-Impact	
	In-use Testing					Indirect	
Audit Trail	Author Identification					Indirect	
	Author Authentication					Direct	
	Sequence Recovery					Direct	
	Approval-Content Link					Direct	
	Retain previous data					Direct	
	Automatic creation					Direct	
	Secure trail storage					Direct	
	Alteration approval					Direct	
Electronic Signature	Signature Capture					Direct	
	Signature Responsibility					Direct	
	Signature Authorisation					Direct	
	Signature Content					Direct	
	Non-transferable identity					Direct	
Record	Disposal Approval					No-Impact	



Record-Reliability Controls

(Ref. SOP VAL 060)

Generic Control Measures		Reliability-attribute supported by Control				Minimum Reference Standard	Assessment - Commentary
		Accurate	Authentic	Available	Integral		
Retention	Defined storage period					Indirect	
	Periodic testing					Indirect	
	Transient copy removal					Indirect	
	Un-editable format					Indirect	
	Human readable form					Indirect	
Software Controls	Data-validity checking					No-Impact	
	Error handling					No-Impact	
	Data transfer protocols					No-Impact	
	Confirmation prompting					Indirect	
	Automated generation					Direct	
	Independent checking					Direct	
Policies, Procedures, Training	Selection & Training					No-Impact	
	Activity History					No-Impact	
	Reviews and Audits					Indirect	
	Defined Responsibilities					Indirect	
	Operational procedures					Indirect	
	Alignment procedures					Direct	

Summary Assessment	<i>Adequacy of Document Reliability Control Measures (and justification):</i> Accuracy: Authenticity: Availability: Integrity: Overall:
---------------------------	--

Suggested Improvements to Control Measures	<i>Identify mitigation tasks that are realistically achievable with the current system and should be considered:</i> Management: Technical: Operational:
---	---

Prepared by		Date:
Reviewed by	'Technical Expert':	Date:
Checked by	Computer Systems Validation Manager or Validation Manager	Date:
Approved by	System Owner:	Date:

Assessment Version	Reason (with reference to Validation Plan/Change Requests)
1.0	New