CVSHealth

Risk Control Analysis
SimpleDose Audit #21170 – April 2021

Control[i]	Design Effectiveness[ii]	Type & Freq.[iii]	Key Control[iv]	Documentation Support	Next Steps[v]
Risk A – Capacity Planning (SO-1) **Technology infrastructure supporting the SimpleDose application is unable to support increased Patient and Pharmacy data volume.**					
A.1 – Capacity Planning System storage for SimpleDose has been addressed to ensure the technology infrastructure is scalable enough to support current and future data volumes. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Partially Effective**	M P As Needed	Yes	Walk-through Minutes Solutions Design and Data Flow	Test = Review Planning documents
A.2 – Event Monitoring SimpleDose storage is monitored by the Application Team with alerts configured for notifying the Data Base Analysts when threshold limits are met. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	A D Continuous	Yes	Walk-through Minutes Solutions Design and Data Flow	Test = Sample Storage Events
Risk C – Change Management (SO-3) **Changes to the production environment are not reviewed, tested, or approved prior to production implementation.**					
C.1 – Approved Changes Changes to critical SimpleDose system files are appropriately documented, tested, and approved prior to deployment. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	M P As Needed	Yes	Walk-through Minutes Change Management Control Standard Example of a Change Ticket SDA Timeline	Test = Validate Change Tickets

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C.2 – Defect Management Identified defects from SDA Phase 1 Major & Minor releases are addressed prior to production. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	M P As Needed	Yes	Walk-through Minutes Change Management Control Standard Example of a Change Ticket SDA Timeline	Test = Address the Management of Defects
C.3 – Vulnerability Management SimpleDose Application code is scanned for vulnerabilities prior to being deployed into the production environment. Identified vulnerabilities are addressed in accordance with corporate policy and procedure. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	A D As Needed	Yes	Walk-through Minutes Change Management Control Standard Example of a Change Ticket SDA Timeline	Test = Validate Vulnerability Testing
Risk E – Application Processing (SO-5) **Without a controlled process for running jobs and for altering job schedules, unauthorized programs could be executed that impact patient information and/or the distribution of pharmaceutical products.**					
E.1 – Job Scheduling Access The ability to create, modify, and delete Job schedules is restricted to authorized personnel. *Control Owners:* William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	M P As Needed	Yes	Walk-through Minutes SDA Application Run Book Solutions Design and Data Flow	Test = Review who can schedule Jobs

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Control[i]	Design Effectiveness[ii]	Type & Freq.[iii]	Key Control[iv]	Documentation Support	Next Steps[v]
E.2 – Job Scheduling Process The process of implementing and scheduling SimpleDose Jobs is based on the Batch Run Book. ***Control Owners:*** William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	M P As Needed	Yes	Walk-through Minutes SDA Application Run Book Solutions Design and Data Flow	Test = Validate using the Batch Run Book
E.3 – Job Scheduling Notifications Application Support Team receives notification for job failures in production (including batch job failures/abends). ***Control Owners:*** William (Bill) Mullins, Director, IT Pharmacy Systems	**Effective**	A D Continuous	Yes	Walk-through Minutes SDA Application Run Book Solutions Design and Data Flow	Test = Review Notifications

[i] Be sure the control mitigates the assigned risk and that all controls have all five components of a control (1. person / process; 2. performing a function; 3. frequency; 4. prevents or detects; 5. evidenced). If one of the five is missing, verify with SME that the component is not otherwise addressed. If so, then note the Control Gap (note what component the control is lacking).

[ii] If all five components of a control are addressed and the control mitigates the risk, then it is an "Effective" control. If it does not mitigate the risk, it might be a process. If it does not include all five, this is a control gap and "Control Gap" should be noted.

[iii] A = Automatic Control (performed by a system); M = Manual Control (performed by a person); D = Detective (the control identifies instances of the realized risk after the fact)
P = Preventative (the control mitigates the risk from occurring); How often is this control performed: Daily (once a day or more); Weekly; Monthly; Quarterly; Annually.

[iv] Key Control: substantially mitigates the risk on its own. Non-Key Control: supports a key control, but cannot wholly mitigate the risk on its own.

[v] Describe the outcome of the test, clearly stating that the control either Passed or Failed the test.