

1. System Identification		Reference Location
System General Description and Intended Use	<ol style="list-style-type: none"> 1. The system is a web enabled document control software application that enables records in electronic form to be created, modified, maintained, archived, retrieved, and transmitted. Records and documents are revision controlled. 2. The architecture and design ensure maximum uptime and security. Since deployment in 2021 production environment, the uptime of application availability based on real time monitoring has demonstrated over 99.999%. 3. Design review with independent reviewer completed in March 2021. 	Shedpaper
System Reference	KAM001 v1.05 – Proprietary Application	Shedpaper
2. System Specification and Validations		
Requirement	Descriptions and Internal Procedure References	
Facility/System Information	<ol style="list-style-type: none"> 1. Self-hosted servers are stored in a physically controlled a controlled secured environment accessible only to Shedpaper personnel. 2. Appropriate facilities controls are in place to address pest control, environmental monitoring, fire, security, video surveillance, and room access monitoring 	
Procedure Reference	WI-0005 (9 pages in length)	Shedpaper
Risk Management File	<ol style="list-style-type: none"> 1. Risk Management Plan (RMP-0001) 2. Risk Management Risk Analysis/Software Hazard, Design and Process Failure analysis (RMW-0001) 3. Risk Controls Identification and evidence of implementation 4. Risk Management Report (RMR-0001) 	
Environment Transfer Protocol/Validation	Transfer-0001 (4 pages in length)	
System Topology / Architecture	SDS-0001 (15 pages in length)	
Design input/Output Matrix	SDS-0001 (15 Pages in length)	
Software Validation	Protocol-0001 (7 pages in length) / Report-0001 (8 pages in length) MVP-0001 (10 pages in length) MVR-0001 (10 pages excluding UAT)	
System User Acceptance Testing	Seventeen (17) UAT Scripts	
21CFR820 Validation	UAT18	
Disaster Recovery	WI-0001 (3 pages in length)/Report-0002 (18 pages including UAT scripts)	
Software Specification	RD-0001 (18 pages in length)	Secure Location