

Proposal Name:		Access control system improvements					Proposer: Deema Mozayen			Initiation Form															
Proposal			Business priority (Mark one in first row, and second row if required)					Change Type (Mark all that apply)																	
<p>The recently upgraded Site Access Control System has been found to generate an excessive number of nuisance door alarms. Some of these are due to inappropriately configured alarm timers in the Sateon Application. Furthermore, many doors have misleading names in Sateon, making it harder to resolve faults and alarms. It is proposed that the Sateon system is reconfigured to correct these issues</p>			Licence to Operate (Regulatory)			Must Do/ Critical			Significant Financial Savings			Other		X	Doc Change			Change Control		X	RFC/ Global Change				
			Sustainability			Associated Quality/SHE/QRM Record number (or N/A)								SHE			LIMS			Maintenance Works Order					
														JDI			Finance								
<p>As Is:</p> <p>A number of doors have misleading names in the Sateon system – making it hard to know which alarms occur and where.</p> <p>All doors are set to alarm after the same duration (10s) regardless of what a door is used for – this results in repeat alarms for goods passages and for the plot 6 reception doors.</p> <p>There are some redundant door controllers that are still connected to Sateon – these present a risk for future disruption and faults.</p> <p>Some access groups grant full access to entire areas, just to facilitate access to small parts of those areas.</p>			To Be:												Impact (Mark all that apply)										
			All doors to be renamed with unambiguous, clear names.												Regulatory					Japanese FMA impacted (Y/N)		N			
			2no door alarm timers to be changed to reflect realistic use – whilst minimising risk of intrusion.												SHE					Quality		X			
			2no redundant door controllers to be disconnected. Drawings and configuration records to be updated accordingly.												Finance (inc. CapEx)					Process Change? (Y/N)		N			
			Access groups to be revised or new ones created, with greater granularity so that access can be obtained for more specific areas without granting blanket access.												Proposal Decision										
			Door reader to be added to Plot 7 entrance glass door and faulty carpark barrier controller to be replaced.												Approved					Declined			Deferred		
Scope (impact)															Proposal Approved as:										
<p>The Site Access Control System is a validated GxP system. However, the reconfiguration of the system, as proposed, will have no impact on product quality or patient safety. The changes to the system will be verified and tested.</p>															Functional										
															Site					X					
															Multi-site										
Benefits (Scorecard Focus Area) (Mark one)															Tracking										
Deliver & Scale for patients		X	Accelerate Digital & Tech Innovation				Great Place to Work								Project reference		(Enter Hive or local PMO reference)								
<p>Removing nuisance alarms will increase the visibility of genuine alarms that may constitute a security or quality risk. The disconnection of redundant door controllers will make the system more secure and reduce the potential for future faults. The revision of access groups will reduce the chance of people unnecessarily accessing the wrong parts of restricted areas – whilst trying to access specific sub-areas.</p>			Will require re-configuration work in Sateon; to be performed by Integra Security Systems. Quotes to be provided accordingly.												CRB Reference		2022-0123								
			Total project cost is expected to be £76,593.70, of which £50,403.60 is attributable to internal resource, £16,677.10 to external resource and £9,513.00 to work to be performed by Integra Security Systems on site.												Target Completion Date		By October 2022								
															Signature etc.										

Project Name:		Access control system improvements					Business Case/Charter					
Success Criteria (Opportunities)		Delivered (Y/N)	Key Milestones					Due Date	Deliver ed (Y/N)			
Door names changed and room numbers added to door register		At project end	Project start date					01/04/2022	At project end			
Revised access groups introduced into Sateon		At project end	PMO, CRB and change control to be initiated					06/05/2022	At project end			
Redundant door controllers disconnected		At project end	Approval of PO for Integra Security Systems					13/06/2022	At project end			
		At project end	Integra to attend site and commence work					13/07/2022	At project end			
		At project end	Verify efficacy of remediation work and software reconfigurations					27/08/2022	At project end			
			Update relevant SOP, configuration records and drawings					08/09/2022	At project end			
			Verify changes and approve documents/drawings					20/09/2022	At project end			
			Close change control					30/09/2022	At project end			
			Project closeout					31/10/2022	At project end			
Key project Risks												
<ul style="list-style-type: none"><<Include the risks which could result from the proposal not being implemented>>Increased likelihood of misdiagnosed door alarms which constitute a continued security and quality risk<<Include any risks which could occur during the implementation of the proposal >>Risk of unanticipated work during implementation of fixes with Integra or during raising of change control and delays during document approvals etc -> could result in schedule delays and increased cost												
Key Assumptions												
<ul style="list-style-type: none">Integra conducts work to schedule, without scope creepQA and validation resource available for change verification, document and drawing approvals												
Strategic Pillar impacted												
Quality and Regulatory Simplification		X	Supply Chain Transformation			Agile and Resilient Supply Network			Advance OE		Enabling Supply	
Develop Next Generation Manufacturing Capability			Smart Factories			Sustainability Leadership			Drive I&D		Life-long learning	

Project Name:		Access control system improvements					Business Case - benefits		
Ongoing Tangible Benefits		Business area benefitting	Planned Annualised benefits			Planned Amount	Realised benefit		
			Year 1	Year 2	Year 3				
N/A – Project is related to compliance and security		N/A – Project is related to compliance and security	N/A – Project is related to compliance and security						
		Totals							
Ongoing Intangible Benefits		Benefit description				Business area benefitting	Delivered? (Y/N)		
Reduced risk of misdiagnosing door alarms		Better diagnosis of door alarms will lead to a better response to access control issues/intrusions that may constitute a security or quality event.				Security, Engineering, QA	At project end		
							At project end		
Expected Financial benefits		Financial Payback							
N/A – Project is related to compliance and security		N/A – Project is related to compliance and security							

Project Name:	Access control system improvements					Business Case- costs	
One Time Project Costs					Costs reviewed? (Y /N)		Close-out
<u>Cost Type</u>	<u>Cost description</u>				<u>Planned Amount (£)</u>	<u>Actual Amount (£)</u>	
Capital items	N/A				N/A	At project end	
Resource (internal at £50/hr)	[total from page 5]*50				£50,403.60	At project end	
Resource (External)	Control Engineering SME hrs*£65 , Validation hrs*65				£16,677.10	At project end	
Other (eg Revenue, disposal, recycling costs)	Remediation and reconfiguration work to be performed by Integra Security Systems				£9,513.00	At project end	
Total					£76,593.70	At project end	
Ongoing Operational Costs							Costs reviewed? (Y/N)
<u>Cost Type</u>	<u>Cost description</u>	<u>Planned Annualised costs (£)</u>			<u>Planned Amount (£)</u>	<u>Actual Amount (£)</u>	
		<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>			
Headcount (FTE)	N/A	N/A	N/A	N/A	N/A	At project end	
Equipment costs	N/A	N/A	N/A	N/A	N/A	At project end	
Maintenance costs	N/A	N/A	N/A	N/A	N/A	At project end	
Depreciation costs (include start, monthly cost, and duration)	N/A	N/A	N/A	N/A	N/A	At project end	
Other (eg Revenue costs)	N/A	N/A	N/A	N/A	N/A	At project end	
Total Annual costs	N/A	N/A				At project end	

Project Name:		Access control system improvements				Resourcing	
Role	Name(s)	Activity	Start date	Finish date	Hrs/Wk	Total project hrs	
PM	██████	Project planning and implementation	01/11/2021	31/10/2022	4	208	
Sponsor	████████	Oversight and steering	01/11/2021	31/10/2022	0.5	26	
PMO	N/A						
SHE	N/A						
Manufacturing	N/A						
SCO	N/A						
QC	N/A						
Eng	Deema Mozayen/ ████████	Project planning and implementation	01/11/2021	31/10/2022	15	780	
	██████████████	Support with raising PMO proposal, CRB and change control	01/03/2022	30/09/2022	3	91	
IT	N/A						
Validation	██	Validation of changes to Sateon system	27/08/2022	30/09/2022	10	50	
BPD	N/A						
Finance	██████	PO for Integra, document and configuration records	01/03/2022	30/09/2022	3	91	
HR&D	N/A						
QA	██	Document and drawing approvals	08/09/2022	20/09/2022	5	19.5	
Tech Services	N/A						
Regulatory	N/A						
Third party	Integra Security Systems Ltd.	Reconfiguration work in Sateon software system, disconnecting redundant door controllers, fixing and adjusting existing ones	13/07/2022	27/08/2022	N/A	Fixed cost for work	