

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 and UKE0130 be updated accordingly.</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)			RE-000832 MA-000509			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>			<p>To Be:</p> <p>All doors to be renamed with unambiguous, clear names.</p> <p>2no door alarm timers to be changed to reflect realistic use – whilst minimising risk of intrusion.</p> <p>2no redundant door controllers to be disconnected. Drawings and configuration records to be updated accordingly.</p> <p>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. UKE0130 to be updated accordingly.</p> <p>Door reader to be added to Plot 7 entrance glass door and faulty carpark barrier controller to be replaced.</p>										Impact (Mark all that apply)					
													Regulatory			Japanese FMA impacted (Y/N)		N
													SHE			Quality		X
													Finance (inc. CapEx)			Process Change? (Y/N)		N
			Proposal Decision															
Approved			Declined			Deferred												
Proposal Approved as:																		
Functional																		
Site										X								
Multi-site																		
Tracking																		
Project reference				(Enter Hive or local PMO reference)														
CRB Reference				2022-0123														
Target Completion Date				By October 2022														
Signature etc.																		
Scope (impact)																		
<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. UKE0130 will be updated along with drawings 6-000-I507, 6-000-I501, 6-000-I500, relevant configuration records and the associated validation report and protocol.</p>																		
Benefits (Scorecard Focus Area) (Mark one)																		
Deliver & Scale for patients		X	Accelerate Digital & Tech Innovation				Great Place to Work											
<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>						<p>Will require re-configuration work in Sateon; to be performed by Integra Security Systems. Quotes to be provided accordingly.</p>												
						<p>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.</p>												

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"><li>&lt;&lt;Include the risks which could result from the proposal not being implemented&gt;&gt;</li><li>Increased likelihood of misdiagnosed door alarms which constitute a continued security and quality risk</li><li>&lt;&lt;Include any risks which could occur during the implementation of the proposal &gt;&gt;</li><li>Risk of unanticipated work during implementation of fixes with Integra or during raising of change control and delays during document approvals etc -&gt; could result in schedule delays and increased cost</li></ul>														
Key Assumptions														
<ul style="list-style-type: none"><li>Integra conducts work to schedule, without scope creep</li><li>QA and validation resource available for change verification, document and drawing approvals</li></ul>														
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	