Part 1: FCCA - System Identification

Page 1 of 14	Way North
ndary Ref.	El Monia

System ID Number	System Name	System Boundary Ref.
072RFG03	Cold Room 3 in Building 72	None

System Description

Building B72 includes three (3) fire wall separated rooms that house three (3) stand alone cold rooms equipped with storage racks for bulk product glass or stainless steel containers. Each of three (3) cold storage rooms are internally fitted with a packaged coldroom system constructed of side wall panels, ceiling with supports, storage racks, air cooling system, and sliding entrance door with strip curtain.

The packaged coldroom system is a complete, fully automated, prefabricated modular installation with cooling circuits, designed to meet the specified performance criteria within operating range of 2 to 5°C for the bulk product storage conditions of 1 to 5°C or 2 to 8°C. The coldroom storage rack configuration is capable of storing pallets with 20 liter glass containers and/or 100 liter stainless steel vessels.

Each cold room is equipped with one (1) primary refrigeration system and one (1) backup system for 100% mechanical redundancy. The refrigeration system consists of two (2) air cooled condensing units located outside of Building 72, four (4) evaporator units located within the interior of the cold room, refrigeration piping from condensing units to evaporator units, and a temperature controller with temperature sensor. Each room is also provided with a circular chart recorder with an independent sensor for monitoring the interior temperature of the Cold Room.

The operation of the Cold Room 1, 2 and 3 are fully automated and controlled by PLC Temperature Controllers that provide hard wired temperature alarms to the B6 Galaxy Alarm Monitoring System. The cold room open door alarm and refrigeration compressors fault alarms are hardwired to the B6 Galaxy Alarm Monitoring System. Additionally, the Refrigeration Compressors fault alarms are hardwired directly to the B72 and B6 Fire Alarm System. The switch over from the primary to the backup refrigeration compressors are performed automatically based on either operator selection or an alarm condition.

Part 2: FCCA - System Classification Approval

Impact on F	Product Quality (check one	3)	Impact on H	SE? (Yes or No)
Direct Impact: 🛛	Indirect Impact / N	lo Impact:	Yes:	No: 🗵
Department	Printed Name		Signature	Date
System Owner	Dean Wehr	6	Dalala.	
End User	Brion Moher for -		9	13 JAN 201
EIT C&Q	JASON BEEVER &	Jana 5		14 Jan 2011
EIT	Allison Cacciatore	J. 3	Lastra	13 JAN 2011
HSE*	Bruce Kilby	Bugel	Hilly	14 TAN 2011
QPQV	Carl Slutter	Alex		1437842011

^{*} Approver for applicable systems only; if Not Applicable, enter NA.

FCCA - Reason for Revision

	Reason for Revision
Section	Revisions (include reason)
System Description	Revised for addition of alarms and replacement of temperature controllers with Programable Logic Controller (PLC).
N/A	Added revision table.
	Changed Criticality Assessment of RFG01 Temperature Control function to Quality Critical. Function is required to achieve or maintain a critical cGMP environment.
Part 3 Function RFG01	Change second function sentence "Function requires local indication of the Temperature and Alarms with audible alarms, as applicable." to "Function requires local indication of the Temperature and Alarms listing displayed, as applicable."
	Added to third function sentence "and Fire Alarm System."
	Clarification. As Left accuracy of temperature control loop must be \pm 0.5°C of NIST traceable calibration standard
Part 3 Function RFG03	Revised for clarification based on open door testing per qualification to "Function requires that the Cold Room temperature operating range is maintained within the 30 minutes of time when door is open during product loading or unloading."
Part 3 Function RFG09	Change "Lead/Lag" to "Redundant".
Part 4 Function RFG01	Delete 4 th function "The system controller shall provide audible alarms". Per URS D004189 no requirement for audible alarms
Part 4 Function RFG01 Page 5	Added to 5 th and 6 th functions "and Fire Alarm System".
Part 4 Function RFG01 Page 6	Added 2 nd function "The system control shall send an alarm to Galaxy System when Compressor 1A or 1B fault is detected. Refer to Part 7 – Alarms and Interlocks".
Part 4 Function RFG01 Page 6	Added 3 rd function "The system control shall send an alarm to Fire Alarm System when Compressor 1A or 1B fault is detected. Refer to Part 7 – Alarms and Interlocks".
Part 4 Function RFG01 Page 6	Clarification. As Left accuracy of temperature control loop must be \pm 0.5°C of NIST traceable calibration standard
Part 4 Function RFG03 Page 7	Changed word "recovers" to "maintaining" as per function description RFG03 on page 3 of 15.
Part 4 Function RFG07 Page 7	Change "30 ft-candles at 30" to "5 ft-candles at 35" as per OSHA Reg 1926.56(a)
Part 4 Function RFG09 Page 8	Change "Lead/Lag" to "Redundant" as per function description RFG09 on page 3 of 15.

FCCA - Reason for Revision (continued)

Part 7 Test Ref A4 Revised to "The system issues an alarm when the compressor does not start within the set time for cooling or shuts down during cooling cycle. Controller displays listing of alarm function as expected. The alarm is received in Labwatch ¹ System, Galaxy and Fire Alarm Systems in B6 SOC."
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Bulk Product Storage Building B72 FCCA for Cold Room 3 Functional and Component Criticality Assessments: B72-RFG03-FCCA-01

Part 3: FCCA - Functional Assessment

Page 2 of 14

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System Name	Name Cold Room 3 in Building 72	om 3 in	n Buile	ding 7	7		System l	System ID Number	072RFG03
		Fm	Functional Assessment (Yes/No)	onal Assessr (Yes / No)	nent	Quality	Quality Non-	HSE	
1 A	Function Description	1	2	3	7	Critical (C-TP)	Critical (NC-TP)	Oritical (NC-TP)	Rationale and Comments
									Function requires that the temperature of cold room chamber is automatically maintained between 2 to 5°C for the bulk product storage conditions.
RFGOI	Temperature Control	Z	>	2	<u> </u>	Σ	<u> </u>		Function requires local indication of the Temperature and Alarms listing displayed, as applicable.
		-	4	-	<u>-</u>	3	J.		Function requires transmission of the critical alarm data to B6 Galaxy System and Fire Alarm System.
est formation and in a plicy to programme person associated associ									Function specifies that 'As Left' accuracy of temperature control loop must be \pm 0.5°C of NIST traceable calibration standard.
RFG02	Temperature Recording	Z	Z	>	7	Ø	Ľ		Function requires that the Cold Room temperature is continuously recorded on a 7 day circular chart for a period of 24 hours per day.
Volcania de la Constantia de C	D			•		3			Function specifies that the Chart Recorder has a minimum resolution of 0.5°C and installed with 100 OHM platinum RTD for three wire connection.
RFG03	Temperature Recovery	z	z	Z	Z	Ø			Function requires that the Cold Room temperature is maintained within operating range for 30 minutes when door is open during product loading or unloading.
RFG04	Controller Access Security	z	z	z	z				Function requires that access levels are properly protected using passwords to access process set up parameters.
RFG05	Entrance Door Security	z	z	z	z		Ø		Function allows for authorized user to open entrance door with access card using card reader and remains lock for unauthorized user.
RFG06	Storage Racks Layout	z	Z	z	z		⊠		Function requires that storage rack configuration layout is in 11 rows by 6 high and 7 rows by 6 high for bulk product containers.
RFG07	Internal Lighting Level	z	z	z	>			Ø	Function specifies that the Internal Lighting Level is greater than or equal to 5 fl-candles at 35 inches above the finished floor.
RFG08	Internal Noise Level	Z	Z	z				Ø	Function specifies that the Permissible Exposure Limit (PEL) for Occupational Noise Exposure is < 85 dBA as an 8-hr TWA.

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Part 3: FCCA - Functional Assessment Continued

Part 3: F	Part 3: FCCA - Functional Assessment Continued	ment (Conti	panu					Page 3 of 14
System Name	Name Cold Room 3 in Building 72	ım 3 ir	1 Buile	ling 7.	2		System ID Number	O Numbe	C 072RFG03
		FIE	Functional Assessment (Yes/No)	ional Assessn (Yes/No)	nent	Quality	Quality Non-	HSE	
Function	Function Description	-	2	8	4	Critical (C-TP)	Critical Critical (NC-TP)	(NC-TP)	Rationale and Comments
RFG09	Redundancy	z	z	Z	Z				Function to maximize equipment and components useful life by providing duplicated equipment with a Redundant operating sequence.
RFG10	Maintainability	Z	z	z	z		\boxtimes		Function will only have an impact on maintenance operations.
RFG	HSE	N	Z	Z	z			Ø	Standard HSE requirements for Cold Room

Functional Assessment Questions (Yes or No):

- 1. Is the function required to achieve or maintain a key, controlled or critical quality attribute or specification of a product, ingredient or material?
 - 2. Is the function required to achieve or maintain a critical cGMP environmental or process support specification?
 - 3. Does the function produce, monitor, evaluate, store or report critical primary data?
- 4. Is the function required to achieve or maintain a specification or to demonstrate compliance with permit or registered HSE-critical parameter?

Part 4:	Part 4: FCCA – Functional Test Plan					Page 4 of 14	of 14
System Name		Cold Room 3 in Building 72	System ID Number		072RFG03		
Function	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	F of Fi	FAT gr
RFG01	The system shall provide a temperature range of 2 to 5°C inclusive for 24 hours.	Verification that the Cold Room Temperature functions as expected.	Cold Room Temperature maintains a temperature range of 2 to 5°C for 24 hour period.	URS D004189 GQ_000863	C-TP		SAT
RFG01	The system shall provide visual indication of temperature at control display.	Verify that control display displays temperature of Cold Room.	Control display function as expected.	Stantec PN: 191000912 Section 13041	C-TP	1	SAT
RFG01	The system shall provide visual indication of alarms at control display.	Verify that control display displays alarms of Cold Room.	Control display function as expected.	Stantec PN: 191000912 Section 13041	C-TP	H	SAT
RFG01	The system control shall send an alarm to Galaxy 3 System and Fire Alarm System when high temperature is detected in the Cold Room.		Refer to Part 7 – Alarms and Interlocks			Table 1	
RFG01	The system control shall send an alarm to Calaxy System and Fire Alarm System when low temperature is detected in the Cold Room.		Refer to Part 7 Alarms and Interlocks				
RFG01	The system control shall send an alarm to Galaxy and Labwatch Systems when Cold Room door is open longer than set time.		Refer to Part 7 – Alarms and Interlocks			No. of the Control of	

Notes:

- 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).

 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).
- 3. B72 alarms connected to Labwatch monitoring system will be tested in separate validation protocols for Labwatch Systems. Galaxy Card Access system in B6 will generate alarm reports.

7172-233-00

Part 4:	Part 4: FCCA - Functional Test Plan Continued	ntinued				Page 5 of 14	of 14
System Name		Cold Room 3 in Building 72	System ID Number		072RFG03		
Function	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT ¹ Or FFT	FAT or sat
RFG01	The system control shall send an alarm to Labwatch System when Compressor 1A or 1B fault is detected.		Refer to Part 7 – Alarms and Interlocks			and the second s	-
RFG01	The system control shall send an alarm to Galaxy System when Compressor 1A or 1B fault is detected.		Refer to Part 7 – Alarms and Interlocks				The state of the s
RFG01	The system control shall send an alarm to fire Alarm System when Compressor 1A or 1B fault is detected.		Refer to Part 7 – Alarms and Interlocks				
RFG01	The 'As Left' accuracy of temperature control loop must be \pm 0.5°C of NIST traceable calibration standard.	Verify that temperature controller accuracy is ±0.5°C of NIST traceable calibration standard by reference to calibration certificate.	Temperature controller accuracy is $\pm 0.5^{\circ}$ C of NIST traceable calibration standard by reference to calibration certificate.	Stantec PN: 191000912 Section 13041 GQ_000863	C-TP ONC-TP	FT	SAT
RFG02	The Cold Room system shall be capable of being monitored by Circular Chart Recorder for a 7 day recording period.	Verify that the Cold Room is equipped with 7 day Circular Chart Recorder.	The system is capable of generating printed chart of temperature data for 24 hours/day over a 7 day period.	URS D004189 GQ_000863	C-TP NC-TP	[SAT
RFG02	The Recorder Chart shall have a minimum increment of 0.5°C minimum.	Verify that the Recorder Chart minimum increment is 0.5°C.	Recorder Chart minimum increment is 0.5°C.	Stantec PN: 191000912 Section 13041	C-TP NC-TP C	L	SAT
RFG02	The Circular Chart Recorder shall be installed with 100 OHM platinum RTD temperature sensor.	Verify that the Circular Chart Recorder temperature sensor is 100 OHM platinum RTD.	Chart Recorder temperature sensor is 100 OHM platinum RTD.	Stantec PN: 191000912 Section 13041	C-TP NC-TP	FI	SAT

- 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).
- 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).

 3. B72 alarms connected to Labwatch monitoring system will be tested in separate validation protocols for Labwatch Systems

 4. Galaxy Card Access system in B6 will generate alarm reports. Fire Alarm System in B6 will generate alarm reports.

Functional and Component Criticality Assessments: B72-RFG03-FCCA-01 Bulk Product Storage Building B72 FCCA for Cold Room 3

Part 4: FCCA - Functional Test Plan Continued

Page 6 of 14

rari 4:	Fart 4: FCCA - Functional Lest Lian Continued				***************************************		
System Name	Name Cold Room 3 in Building 72	in Building 72	System ID Number		072RFG03		
Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-IP or NC-IP	FI ¹	FAT or sat
RFG03	When Cold Room door is open, the Cold Room temperature maintaining to operating range within the specified time.	Verify that temperature is maintained within operating range when door is open for 30 minutes.	Temperature is maintained within operating range when door is open for 30 minutes.	URS D004189	C-TP NC-TP		SAT
RFG04	The system control shall be properly protected using passwords to access process set up parameters.	Verify that the access to controller set up parameters functions as required	Access to controller set up parameters is password protected.	Stantec PN: 191000912 Section 13041	C-TP ONC-TP 🛛	IFT.	SAT
RFG05	The entrance door to Cold Room shall unlock with card reader allowing access to authorized card user only.	Verify that the access to entrance door with card reader functions as required.	The entrance door of the Cold Room is opened by authorized users and remains locked for unauthorized card users.	Stantec PN: 191000912 Section 13041	C-TP		SAT
RFG06	The Cold Room storage rack layout shall be configured in 11 rows by 6 high and 7 rows by 6 high.	Verify that the storage rack layout installation is as required.	The storage rack configuration layout is in 11 rows by 6 high and 7 rows by 6 high.	Stantec PN: 191000912 Section 13041	C-TP NC-TP	Ŧ	SAT
RFG07	The Cold Room Internal Lighting Level shall be greater than or equal to 5 ft-candles at 35 inches above the finished floor.	Verify that the Cold Room Internal Lighting Level meets or exceeds 5 ft-candles at 35 inches above the finished floor.	Internal Lighting Level meets or exceeds requirements.	OSHA 1926.56(a)	C-TP		SAT
RFG08	The Cold Room Permissible Exposure Limit (PEL) for Internal Noise Level is <85 dbA.	Verify that the Cold Room Internal Noise Level is lower than 85 dbA.	Internal Noise Level is lower than requirements.	URS D004189	C-TP	L	SAT
RFG09	The Cold Room refrigeration equipment shall be provided with duplicate units.	Verify that the refrigeration units are duplicate.	The refrigeration equipment is installed with duplicate units.	Stantec PN: 191000912 Section 13041 URS D004189	C-TP	L	SAT
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Notes:

^{1.} FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).

^{2.} FAT or \$AT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).

Bulk Product Storage Building B72 FCCA for Cold Room 3
Functional and Component Criticality Assessments: B72-RFG03-FCCA-01

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Part 4:

Page 7 of 14

System Name		Cold Room 3 in Building 72	System ID Number	A for many of management of the party of the state of the	072RFG03		
Function	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT ¹ or IFT	FAT or SAT
RFG09	The Cold Room refrigeration units shall be set up with Redundant operating sequence.	Verify that the refrigeration units Redundant functions as required.	Refrigeration units Redundant function as expected.	Stantec PN: 191000912 Section 13041 URS D004189	C-TP □	Çonud Line Sound	SAT
RFG10	All equipment and instrumentation requiring maintenance must be safely accessible (1 Meter path clearance) and be readily removable without major disassembly or disrupting the system or other systems.	Verify that the equipment and instrumentation are accessible and removable.	Equipment and instrumentation are accessible and removable.	Stantec PN: 191006912 Section 13041 21 CFR211.63	C-TP	Ī	SAT
RFG11	The Cold Room control and refrigeration system shall be connected to emergency power with a UPS to provide uninterrupted power and continued operation during loss of normal electrical power.	Verify that the Cold Room control and refrigeration system is connected to UPS and Emergency Power Generator.	The control and refrigeration system is powered via Emergency Power Generator and is connected to UPS.	Stantec PN: 191000912 Section 13041 URS D004189	C-TP	Ē	SAT

Notes:

- 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).
- 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).

Part 5: FCCA – Critical Components Materials of Construction (MOC) Page 8 of 14

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03
P&ID Tag No.	Component Description	Specified Material of Construction	Additional Specifications
N/A	Refrigerant for Refrigeration Compressors	R404A	MSDS Sheet
N/A	Cold Room Walls and Ceiling Panels	Maximum Flame Speed 25 and Smoke Developed Rate 450	NEPA

The Cold Room 3 in Building 72 does not include any direct product contact materials of construction.

Instrument P&ID Tag # Descr		Koom 2 i	Cold Koom 5 in Building /2	7/50	5	System 1D Number	
P&ID Tag # Desc		Instrui Asses	Instrument Criticality Assessment (Y/N) ¹	cality N) ¹	IIF Criticality		
P&ID Tag # Desc		Quality	Ę	HSE	Classification	Normal Operating	
	Description	T	2	ဗ	7	Range	Rationale and Comments
072RFG03TIC0101 Temperature Indicating Controller	dicating	Z	Y	Z	Process Critical	1-8°C	The failure of this instrument will have a direct impact on the temperature within Cold Room.
072RFG03TIR0101 Recorder	rdicating Chart	, X	Z	z	Product Critical	1-8°C	Readings recorded in logbook. The failure of this instrument will not have a direct impact since each cold room has discrete temperature monitoring devices.

1. Product Critical -KPP/CPP (Quality): Would failure of this instrument have direct effect on product quality, safety, purity or efficacy?

2. Process Critical - COP (Quality): Would failure of this instrument have a direct or measurable impact on a process parameter (e.g., temperature, humidity, pressure)?

3. HSE Critical: Would the failure of this instrument have a direct impact on safety or the environment?

4. IF Criticality Classification: If 'Y' was entered in Columns 1 or 2, enter the criticality type(s) as Product Critical or Process Critical. If 'Y' was entered in Column 3, enter the criticality type as HSE Critical. If "N" was entered in Columns 1, 2 and 3, enter "NC (for Non-critical) or 'PCNR' (for Periodic Calibration Not Required).

Bulk Product Storage Building B72 FCCA for Cold Room 3

Functional and Component Criticality Assessments: B72-RFG03-FCCA-01

Page 10 of 14

Ref A4 A3 A2Al Labwatch¹ System, Galaxy and Fire Alarm Systems in The system issues an alarm when the Cold Room door The system issues an alarm when the compressor does not start within the set time for cooling or shuts down is open longer than set time. The alarm is received at alarm function as expected. The alarm is received in 072RFG03 temperature is higher than high alarm set point. The during cooling cycle. Controller displays listing of temperature is lower than low alarm set point. The alarm is received at Galaxy1 System in B6 Security The system issues an alarm when the Cold Room The system issues an alarm when the Cold Room alarm is received at Galaxy System in B6 SOC. Acceptance Criteria Galaxy System in B6 SOC. Operations Center (SOC). System ID Number B6 SOC. Verify alarm Verify alarm Verify alarm Verify alarm functions as functions as functions as functions as Test Case expected. expected. expected. expected. Alarm Criticality Classifications HSE Critical П ø NCTP Quality Non-Critical Cold Room 3 in Building 72 \boxtimes \boxtimes w. Quality Critical CIP \boxtimes 4 \boxtimes Critical 22 Z er) Z. Z Z Data? (V/N) \mathbf{Z} Z z Z Controlor rı Alarm on Critical Primary Critical Part 7: FCCA - Alarms and Interlocks Z Z > × Cold Room 3 Compressor 1A or 1B Fault Cold Room High Temperature Cold Room Low Temperature Cold Room Door Open Description System Name Alarm #01 Y/Z $\stackrel{\checkmark}{\sim}$ Ϋ́ ₹ Z

1. Product Critical (KPP/CPP): Would the failure of this alarm have direct effect on product quality, safety, purity or efficacy?

2. Process Critical (COP): Would the failure of this alarm have a direct or measurable impact on a process parameter (e.g., temperature, humidity, pressure)?

3. HSE Critical: Would the failure of this alarm have a direct impact on safety or the environment?

4. If 'Y' for Yes was entered in Columns 1 and/or 2, check (X) the Quality Critical/C-TP column.

5. If 'N' for No was entered in both Columns 1 and 2, check (X) the Quality Non-Critical/NC-TP column.

6. If 'Y' for Yes was entered in Column 3, then check (X) for HSE Critical/NC-TP column.

1872 alarms connected to Labwatch monitoring system will be tested in separate validation protocols for Labwatch Systems. Galaxy Card Access system in B6 will generate alarm reports.

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Functional and Component Criticality Assessments: B72-RFG03-FCCA-01 Bulk Product Storage Building B72 FCCA for Cold Room 3

System Name Cold Room 3 in Building 72	Iding 72	System ID Number	Number	072RFG03	C03
			Mechanical Completion	•	
Document Identification	Required? (Yes/No)	Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	Required for C-TP
P&IDs	N N X	100%			44.50
Air Flow / Air Balancing Diagram	N M N	100%			-
Isometric Drawings (3D)	N N N	100%			1
Equipment & Component Detail Drawings	N N	Spot Check			-
Control Panel Drawings	N N N	Spot Check			
Control System Wiring Diagrams	N N N	Spot Check			
Control System Architecture Drawings	N N N	100%		(5)	
Network Architecture Diagrams	N N N	100%		4/3	44 74
Pneumatic Distribution Diagrams	N N N	Spot Check		/A Z3 MARZOU	and with
Loop or Segment Drawings	N N N	Spot Check			4. 4.
Electrical Panel Drawings	Z Z Z	Spot Check			
Electrical Wiring Diagrams & Schematics	N N	Spot Check			
*Material of Construction Certificates	N N D	100%			***
Instrument Cut Sheets	N N	Spot Check			
Mechanical Component Cut Sheets	N N	Spot Check			# #
Gasket and O-Ring Spec Sheets	N N N	Spot Check			
*Lubricant List	N N L	100%			lar sår.

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A005120 7172-233-00

Bulk Product Storage Building B72 FCCA for Cold Room 3 Functional and Component Criticality Assessments: B72-RFG03-FCCA-01

Part 8: FCCA - Document Verification	fication				***************************************	rage 13 01 14
System Name	Cold Room 3 in Buildi	ding 72	System ID Number	Number	072RFG03	303
				Mechanical Completion		
Document Identification	fication	Required? $(\underline{X}es/\underline{N}o)$	Andit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	Required for C-TP
*Weld Procedure Qualification		OY NN	100%			
*Weld Procedure Specifications		N N	100%			/
*Welding Operator Qualification		N N U	100%			
*Weld Maps		N N	100%			-
*Weld Logs		N N N	100%			-
*Weld Filler Material Datasheets	AND THE PROPERTY OF THE PROPER	N ⊠ N □	100%			-
*Weld Purge Gas Certificates of Analysis	llysis	N N N	100%			marane.
*Cleaning and Passivation Records		N N	100%		NA	1
*Electro polishing Certificate		N 🛭	100%		1/4 23 MARIZEON	*****
*Surface Finish Test Report		N N D	100%			
Pressure Vessel Code Certificate		N N N	100%			i i
Relief Device Certificates		N N N	100%			THE PART
Hydrostatic Test Certificate		N⊠ Y□	100%			1
Pneumatic Pressure Test Certificate		N N N	100%			L
*Drainage Test Records	A THE PROPERTY OF THE PROPERTY	N N N	100%			1
*Slope Verification Records		N N N	100%			ļ
Required for Direct Impact Systems Only	Lakesiti, en merrinamen menemen menemen erinari perinari da karaman menemen menemen menemen menemen menemen men V	AND THE RESIDENCE AND A LABORATED AND ADMINISTRATION OF THE RESIDENCE AND ADMINISTRATION OF THE PROPERTY OF TH				

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Bulk Product Storage Building B72 FCCA for Cold Room 3 Functional and Component Criticality Assessments: B72-RFG03-FCCA-01

Part &: FCCA - Document Verification	IICAUOII					
System Name	Cold Room 3 in Building 72	ling 72	System ID Number	Number	072RFG03	C03
				Mechanical Completion		
Document Identification	fication	Required? $(\underline{Y}es/\underline{N}o)$	Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials/Date	Required for C-TP
Alarm and Interlock List		N N N	Spot Check			
Sequence of Operations		N N N	Spot Check			
Ladder Logic Diagram	A CANADA THE RESIDENCE AND A CANADA THE RESIDENC	N N L	Spot Check			
Configuration Data Sheets		\square \square \square	100%		5/4	Liver 1
Software Configuration Reports		N N N	100%		WA- 23 MABLOW	1
Software Unit/Integration Test Results	\$1	N M N	100%			-
Installation, Operation and Maintenance Manuals (O&M)	nce Manuals (O&M)	N N N	100%			1
Refrigerant Data Sheet		N N N	100%			1
Wall and Ceiling Material Data Sheet		N N N	100%			

^{*} Required for Direct Impact Systems Only



Part 1: FCCA - System Identification

Page 1 of 14

System ID Number	System Name	System Boundary Ref.
072RFG03	Cold Room 3 in Building 72	None

System Description

Building B72 includes three (3) fire wall separated rooms that house three (3) stand alone cold rooms equipped with storage racks for bulk product glass or stainless steel containers. Each of three (3) cold storage rooms are internally fitted with a packaged coldroom system constructed of side wall panels, ceiling with supports, storage racks, air cooling system, and sliding entrance door with strip curtain.

The packaged coldroom system is a complete, fully automated, prefabricated modular installation with cooling circuits, designed to meet the specified performance criteria within operating range of 2 to 5°C for the bulk product storage conditions of 1 to 5°C or 2 to 8°C. The coldroom storage rack configuration is capable of storing pallets with 20 liter glass containers and/or 100 liter stainless steel vessels.

Each cold room is equipped with one (1) primary refrigeration system and one (1) backup system for 100% mechanical redundancy. The refrigeration system consists of two (2) air cooled condensing units located outside of Building 72, four (4) evaporator units located within the interior of the cold room, refrigeration piping from condensing units to evaporator units, and a temperature controller with temperature sensor. Each room is also provided with a circular chart recorder with an independent sensor for monitoring the interior temperature of the Cold Room.

The operation of the Cold Room is fully automated and controlled by the Temperature Controller. Switch over from the primary to the backup system is performed automatically based on either a duration timer or an alarm condition.

Part 2: FCCA - System Classification Approval

Impact on P	roduct Quality (check on	e)	Impact on HS	SE? (Yes or No)
Direct Impact: 🗵	Indirect Impact / N	No Impact: 🔲	Yes:	No: 🗵
Department	Printed Name		Signature	Date
System Owner	Dean Wehr	Den 1	alleh	09 oct 2010
End User	Joan Corcia	40		04007201
EIT C&Q	Mike Polansky	Mel	12	Hatrus
EIT	Allison Cacciatore	aleison	aeciatre	04 Oct 2010
HSE*	Bruce Kilby	Szeleih:	- for Bened Kill	by 040cTzo10
QPQV	Carl Slutter	12/9/	ν	04027 2016

^{*} Approver for applicable systems only; if Not Applicable, enter N/A.



Part 3: FCCA - Functional Assessment **~**

	THE RESERVENCE OF THE PROPERTY				
System Name	Cold Room 3 in Building 72	ng 72	System ID Number	072RFG03	A PARTICIPATION OF THE PROPERTY OF THE PARTICIPATION OF THE PARTICIPATIO
Concession of the Concession o	Functional Assessmen	sessment	Ouality		
	(Yes / No)	(o) Quality	Non-		25 u 1
unction		Critical	Critical Critical		

System Name	Name Cold Room 3 in Building 72	om 3 ir	1 Builk	ling 7.	۲۵		System I	System ID Number	r 072RFG03
		Ē	Functional Assessment (Yes / No)	onal Assessn (Yes / No)	nent	Quality	Outality Non-	HSE	
Function	Function Description	***	7		4		(NC-TB)	(NC-TP)	Rationale and Comments
									Function requires that the temperature of cold room chamber is automatically maintained between 2 to 5°C for the bulk product storage conditions.
8	Temperature Control	Z	Z.	Z	Z		×	О	Function requires focal indication of the Temperature and Atalias with authore alarms, as applicable.
									Function requires transmission of the critical alarm data to B6 Galaxy System. Function specifies that accuracy of the correlation between temperature set point and true temperature resulting from setting shall be plus or minus 0.5°C.
					,	[[Function requires that the Cold Room temperature is continuously recorded on a 7 day circular chart for a period of 24 hours per day.
RF 002	Temperature Recording	Z	Z.	>-	Z	⊠ .			Function specifies that the Chart Recorder have a minimum resolution of 0.5°C and installed with 100 OHM platinum RTD for three wire connection.
	Temperature Recovery	Z	Z	Z	Z	\boxtimes			Function requires that the Cold Room temperature recovers to operating range within the specified time when door is open during product loading or unloading.
RFCWA	Controller Access Security	z	z	z	z		×		Function requires that access levels are properly protected using passwords to access process set up parameters.
RFG05	Entrance Door Security	Z	z	z	Z		×		Function allows for authorized user to open entrance door with access card using card reader and remains lock for unauthorized user.
RFGB	Storage Racks Layout	Z	z	Z	Z		×		Function requires that storage rack configuration layout is in 11 rows by 6 high and 7 rows by 6 high for bulk product containers.
RFG07	Internal Lighting Level	z	72	Z.	X			⊠	Function specifies that the Internal Lighting Level is greater than or equal to 5 ft-candles at 36 inches above the finished floor.
RFC08	Internal Noise Level	z	Z	z	>			⊠	Function specifies that the Permissible Exposure Limit (PEL) for Occupational Noise Exposure is < 85 dBA as an 8-hr TWA.
ALABAMAAAAAAAAAAAAAAAAAAAAAAAA	yearshow Assistant Annual Management of the Control of the North Control of the C	- AVENUAL DESIGNATION OF THE PERSON OF THE P							

Part 3: FCCA - Functional Assessment Continued

Page 3 of 14

System Name	Vame Cold Room 3 in Building 72	om 3 in	Build	ling 7.	۷,	-	System I	System ID Number	r 072RFG03
and a second second		ğ	Functional Assessment (Yes / No)	Assessii No)	lent	Quality	Quality Non-	HSE	
Function	Function Description	-	77	(43	4			NC-TP) (NC-TP)	Rationale and Comments
RFG09	Redundancy	Z.	z	z	z		X		Function to maximize equipment and components useful life by providing duplicated equipment with a Lead/Lag operating sequence.
RFG10	Maintainability	Z	z	z	z		×		Function will only have an impact on maintenance operations.
RFGH	HSE	Z.	z	z	z			×	Standard HSE requirements for Cold Room

Functional Assessment Questions (Yes or No):

- 1. Is the function required to achieve or maintain a key, controlled or critical quality attribute or specification of a product, ingredient or material?
 - 2. Is the function required to achieve or maintain a critical cGMP environmental or process support specification?
 - 3. Does the function produce, monitor, evaluate, store or report critical primary data?
- 4. Is the function required to achieve or maintain a specification or to demonstrate compliance with permit or registered HSE-critical parameter?

Functional and Component Criticality Assessments: B72-RFG03-FCCA-01 Bulk Product Storage Building B72 FCCA for Cold Room 3

Part 4: FCCA - Functional Test Plan

Page 4 of 14

FAT" SAT SAT SAT SAT S IF. FT F Ę 072RFG03 NC-TP C-TP NC-TP NC-TP C-TP ö C-TPC-TP Section 13041 GQ_000863 191000912 191000912 Stantec PN: Stantec PN: Acceptance D004189 Criteria Source URS temperature range of 2 to 5°C for 24 hour period. Cold Room Temperature maintains a Control display function as expected. System ID Number Acceptance Criteria Verify that control display displays Temperature functions as expected. Verification that the Cold Room temperature of Cold Room. Test Case Cold Room 3 in Building 72 The system shall provide visual indication The system shall provide visual indication range of 2 to 5°C inclusive for 24 hours. The system shall provide a temperature of temperature at control display. Description System Name Function ID RFG01 **RFG01**

SAT

IFT

C-TP C-TP NC-TP

Section 13041

Control display function as expected.

Verify that system controller

provides audible alarms.

Galaxy System when high temperature is

RFG01

detected in the Cold Room.

The system control shall send an alarm to

The system controller shall provide audible alarms.

RFG@1

of alarms at control display.

RFG01

The system control shall send an alarm to

Galaxy System when low temperature is

RFG03

detected in the Cold Room.

The system control shall send an alarm to

Cold Room door is open longer than set

Galaxy and Labwatch Systems when

RFG01

Control display function as expected.

Verify that control display displays

alarms of Cold Room.

Refer to Part 7 - Alarms and Interlocks

Refer to Part 7 - Alarms and Interlocks

NC-TP

Section 13041

Stantec PN: 191000912

Notes:

- 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (FAT).

 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).

Refer to Part 7 - Alarms and Interlocks

3. B72 alarms connected to Labwatch monitoring system will be tested in separate validation protocols for Labwatch Systems. Galaxy Card Access system in B6 will generate alarm reports.

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Page 5 of 14

Functional and Component Criticality Assessments: B72-RFG03-FCCA-01 Bulk Product Storage Building B72 FCCA for Cold Room 3

Part 4: FCCA - Functional Test Plan Continued

FAT SAT SAT SAT SAT or SAT IFT 1 a H H 072RFG03 \boxtimes C-TP \times NC-TE NC-TP NC-TP NC-TP NC-TP C-TP C-TP \boxtimes C-TP Stantec PN: 191000912 Section 13041 Section 13041 GQ_000863 GO 000863 Stantec PN: 191000912 Acceptance 191000912 Stantec P.N. D004189 Criteria Source URS Refer to Part 7 - Alarms and Interlocks chart of temperature data for 24 hours/day over a Chart Recorder temperature sensor is 100 OHM Recorder Chart minimum increment is 0.5°C. The system is capable of generating printed Controller accuracy is plus or minus 0.5°C. Acceptance Criteria System ID Number 7 day period. Recorder temperature sensor is 100 OHM platinum RTD. equipped with 7 day Circular Chart Verify that temperature controller accuracy is plus or minus 0.5°C. Verify that the Recorder Chart Verify that the Circular Chart minimum increment is 0.5°C. Verify that the Cold Room is Test Case Cold Room 3 in Building 72 Recorder. temperature resulting from the setting shall be plus or minus 0.5°C. The Cold Room system shall be capable of The Recorder Chart shall have a minimum Labwatch System when Compressor 1A or The system control shall send an alarm to The system control accuracy between the Recorder for a 7 day recording period. The Circular Chart Recorder shall be being monitored by Circular Chart temperature set point and the true increment of 0.5°C minimum. Description 1B fault is detected System Name Function RFG02 RFG02 RFG01 RFG01

Notes

1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).

Section 13041

platinum RTD.

installed with 100 OHM platinum RTD

RFG02

temperature sensor.

2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).



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Page 6 of 14

Part 4: FCCA - Functional Test Plan Continued

System Name	Name Cold Room 3 in Building 72	n Building 72	System ID Number		072RFG03		
Function	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C.TP or NC.TP	- E = E	FAT SAT
RFG03	When Cold Room door is open, the Cold Room temperature recovers to operating range within the specified time.	Verify that temperature recovers to operating range when door is open for 30 minutes.	The system is capable of temperature recovery to operating range after 1 hour from door closing.	URS D004189	C-TP NC-TP		SAT
RFG04	The system control shall be properly protected using passwords to access process set up parameters.	Verify that the access to controller set up parameters functions as required	Access to controller set up parameters is password protected.	Stantec PN: 191000912 Section 13041	C-TP	<u> </u>	SAT
RFG05	The entrance door to Cold Room shall unlock with card reader allowing access to authorized card user only.	Verify that the access to entrance door with card reader functions as required.	The entrance door of the Cold Room is opened by authorized users and remains locked for unauthorized card users.	Stantec PN: 191000912 Section 13041	C-TP	[SAT
RFG06	The Cold Room storage rack layout shall be configured in 11 rows by 6 high and 7 rows by 6 high.	Verify that the storage rack layout installation is as required.	The storage rack configuration layout is in 11 rows by 6 high and 7 rows by 6 high.	Stantec PN: 191000912 Section 13041	C-TP		SAT
RFG07	The Cold Room Internal Lighting Level shall be greater than or equal to 30 ft-candles at 30 inches above the finished floor.	Verify that the Cold Room Internal Lighting Level meets or exceeds 30 ft-candles at 30 inches above the finished floor.	Internal Lighting Level meets or exceeds requirements.	URS. D004189	C-TP		SAT
RFG08	The Cold Room Permissible Exposure Limit (PEL) for Internal Noise Level is <85 dbA.	Verify that the Cold Room Internal Noise Level is lower than 85 dbA.	Internal Noise Level is lower than requirements.	URS D004189	C-TP	in the second se	SAT
RFG09	The Cold Room refrigeration equipment shall be provided with duplicate units.	Verify that the refrigeration units are duplicate.	The refrigeration equipment is installed with duplicate units.	Stantec PN: 191000912 Section 13041 URS D004189	C-TP	Ш	SAT

Notes

- 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).
- 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT).

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Page 7 of 14

Functional and Component Criticality Assessments: B72-RFG03-FCCA-01 Bulk Product Storage Building B72 FCCA for Cold Room 3

J Tast Plan Confinued . r

Dort A.	Dart de WCCA — Functional Test Plan Continued	Ontinued	AMERICAN PROPERTY AND ASSESSMENT OF THE PROPERTY OF THE PROPER	THE PARTY OF THE P			
1 41 4 3 4	S. Variation of the control of the c	2 D:Linn 72	System ID Number		072KFG03		
System Name		Cold Room 5 in Building /2		The state of the s	dI-O	ET.	FAT ²
Function	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	NC-TP	LE G	er SAT
RFG09	The Cold Room refrigeration units shall be set up with Lead/Lag operating sequence.	Verify that the refrigeration units Lead/Lag functions as required.	Refrigeration units Lead/Lag function as expected.	Stantec PN: 191000912 Section 13041 URS D004189	C-TP	Larry Like Same	SAT
RFG10	All equipment and instrumentation requiring maintenance must be safely accessible (1 Meter path clearance) and be readily removable without major disassembly or disrupting the system or	Verify that the equipment and instrumentation are accessible and removable.	Equipment and instrumentation are accessible and removable.	Stantec PN: 191000912 Section 13041 21 CFR211.63	C-TP	fason Lives	SAT
	other systems.			Comment DAY.		No. of the last of	
RFG	The Cold Room control and refrigeration system shall be connected to emergency power with a UPS to provide uninterrupted power and continued operation during loss of	Verify that the Cold Room control and refrigeration system is connected to UPS and Emergency Power Generator.	The control and refrigeration system is powered via Emergency Power Generator and is connected to UPS.	Stantec FW. 191000912 Section 13041 URS D004189	C.TP		SAT
	normal electrical power.	A PARTY OF THE PAR					

Notes:

- 2. FAT or SAT denotes the earliest point at which that testing can be captured; Factory Acceptance Testing (FAT) or On-Site Acceptance Testing in Swiftwater (SAT). 1. FT or IFT denotes that testing may be included in either Functional Testing (FT) or Integrated Functional Testing (IFT).



Part 5: FCCA - Critical Components Materials of Construction (MOC) Page 8 of 14

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03
P&ID Tag No.	Component Description	Specified Material of Construction	Additional Specifications
N/A	Refrigerant for Refrigeration Compressors	R404A	MSDS Sheet
N/A	Cold Room Walls and Ceiling Panels	Maximum Flame Speed 25 and Smoke Developed Rate 450	NEPA

The Cold Room 2 in Building 72 does not include any direct product contact materials of construction.



Page 9 of 14

Cold Room 3 in Building 72 hastrument Criticality IIF Criticality Assessment (Y/N) IIF Criticality Assessment (Y/N) IIF Criticality Range Range I 2 3 4 Range Range I 1-8°C dicating Chart Y N Product Critical I -8°C Instrument Criticality Classifications I -8°C I -8°C	Part 6: FCCA - Instruments	And the second s		A STATE OF THE STA			Contour III Number	072RFG03
Instrument Criticality Normal Operating Controller N Y N Process Critical 1-8°C Temperature Indicating Chart Y N Product Critical 1-8°C Recorder Product Critical 1-8°C			dd Room 3	in Buildin	g 72		System 10 Carriers	
Quality HSE Classification Normal Operating Description t 2 3 4 Range Temperature Indicating Chart N Y N Product Critical 1-8°C Temperature Indicating Chart Y N N Product Critical 1-8°C		Instrument	Instru Asse	ment Criti ssment (Y/	cality N - N	(IR Criticality		
Temperature Indicating Chart Y N Process Critical 1-8°C Controller Temperature Indicating Chart Y N Product Critical 1-8°C Recorder			One	A A	HSE	Classification	Normal Operating Range	Rationale and Comments
Controller Temperature Indicating Chart y N N Product Critical 1-8°C Recorder Product Critical 1-8°C	PAID FAE#	Description Temperature Indicating	7	>) Z	Process Critical		The failure of this instrument will have a direct impact on the temperature within
Temperature Indicating Chart Y N N Product Critical 1-8°C Recorder	072RFC03TEC0301	Controller		•		A A A A A A A A A A A A A A A A A A A		Cold Room. Readings recorded in logbook. The failure
Recorder Character Criticality Classifications	And the state of t	Temperature Indicating Chart	>	Z	Z	Product Critical		of this instrument will not have a direct impact since each cold room has discrete
1 instrument Criticality Classifications	072RGF031R030L	Recorder	•					temperature monitoring devices.
				Instr	ument Crit	cality Classificatio	#S	

1. Product Critical -KPP/CPP (Quality): Would failure of this instrument have direct effect on product quality, safety, purity

2. Process Critical - COP (Quality): Would failure of this instrument have a direct or measurable impact on a process parameter (e.g., temperature, humidity, pressure)?

3. HSE Critical: Would the failure of this instrument have a direct impact on safety or the environment?

4. HF Criticality Classification: If 'Y' was entered in Columns 1 or 2, enter the criticality type(s) as Product Critical or Process Critical. If 'Y' was entered in Column 3, enter the criticality type as HSE Critical. If "N" was entered in Columns 1, 2 and 3, enter "NC (for Non-critical) or "PCNR" (for Periodic Calibration Not Required).

Page 10 of 14

Part 7: E	Part 7: FCCA - Alarms and Interlocks	ocks				***************************************		And and springer of the last of the property of the last of th	, , , , , , , , , , , , , , , , , , ,	
ALL PARTY OF THE P	System Name	A STATE OF THE PARTY OF THE PAR	ပ္	Cold Room 3 i	3 in Building 72	ing 72		System	System ID Number	
AND A AND WITH THE A AND AND THE PLANT THE THE THE THE THE THE THE THE THE TH		Alarm on Critical	n on ical		Quality Critical	Quality Non- Critical	HSE			
	a annual control of the control of t	Critical	ical	HSE Critical						ž
	Alarm	Data? (Y/N)	(N/N)	S	C-TP		NC-1F	Truck Coop	Acceptance Criteria	Ref
76	Description	-	7	m	4	'n	9	I est case	and blog and	
* EX	Cold Room High Temperature	>	Z	z	×			Verify alarm functions as expected.	The system issues an alarm when the Cold Acount temperature is higher then high alarm set point. Controller audible alarm function as expected. The alarm is received at Galaxy ¹ System in B6 Security Operations Center (SOC).	- VI
N/A	Cold Room Low Temperature	>	Z	Z				Verify alarm functions as expected.	The system issues an alarm when the Cold Room temperature is lower then low alarm set point. Controller audible alarm function as expected. The alarm is received at Galaxy System in B6 SOC.	A2
**************************************	Cold Room Door Open	Z	Z	Z				Verify alarm functions as expected.	The system issues an alarm when the Cold Room door is open longer than set time. Controller audible alarm function as expected. The alarm is received at Galaxy	A3
	The state of the s							***************************************	System in B6 SCA. The evertem issues an alarm when the compressor does	
W/N	Cold Room 1 Compressor 1A or 1B Fault	Z	Z	Z				Verity alarm functions as expected.	not start within the set time for cooling. Controller audible alarm function as expected. The alarm is received in Labwatch ¹ System in B6 SOC.	A4
And the second s	AN ARTHUR THE STREET OF THE ST						Y datamatch S	vereins Galaxy C	Card Access system in B6 will generate alarm reports.	

¹B72 alarms connected to Labwatch monitoring system will be tested in separate validation protocols for Labwatch Systems. Galaxy Car

and Interlocks Continued

Page 11 of 14

	0/2KFG03	A CONTRACTOR OF THE PROPERTY O		T est	Acceptance Criteria Ref			And a Company of the
THE PERSON NAMED AND PARTY OF THE PE	System ID Number	AMERICAN PROPERTY OF THE PROPE			Treet Casa Acceptant			r efficacy?
	.7.3	7/51	Quality HSE Non- Critical	an con	NC-1F	5 6	Alarm Criticality Classifications	1
	The Contract	7/ Simming III C	Quality Critical		C-14	4	Alarm C	- T
	4 × ×	Cold Koom 5		HSE Critical	(S/S)	m		
	The state of the s	ن	Alarm on Critical Control or	Critical Primary	Data? (Y/N)	7		White the same of
Done Mr. ROCA - Alarms and Interlocks Continued		System Name			Alarm	Description		The state of the s
D	Lant to 1.					*41		

2. Process Critical (COP): Would the failure of this alarm have a direct or measurable impact on a process parameter (e.g., temperature, humidity, pressure)? 1. Product Critical (KPP/CPP): Would the failure of this alarm have direct effect on product quality, safety, purity or efficacy?

3. HSE Critical: Would the failure of this alarm have a direct impact on safety or the environment?

4. If 'Y' for Yes was entered in Columns 1 and/or 2, check (X) the Quality Critical/C-TP column.

5. If 'N' for No was entered in both Columns 1 and 2, check (X) the Quality Non-Critical/NC-TP column.

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Page 13 of 14

Part 8: FCCA - Document Vernication			System ID Number	Number	20 TATY / D	
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Confidential/Proprietary Information Page 13 of 14

Part 8: FCCA - Document Verification	t Verification		C. St. Th Number	Number	072RFG032	.032
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System rams				Mechanical Completion	And the state of t	Deswined for
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