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

Part 1: FCCA – System Identification

15 Wrong Number of pages RM 14 JAN 11

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 Product Quality (check one)		**Impact on HSE?** (Yes or No)	
Direct Impact: ☒	**Indirect Impact / No Impact:** ☐	**Yes:** ☐	**No:** ☒

Department	Printed Name	Signature	Date
System Owner	Dean Wehr		13 JAN 2011
End User	Brian Moher for Joan Corcia		14 JAN 2011
EIT C&Q	JASON BECHER for Mike Polansky		13 JAN 2011
EIT	SANTU MAITRA for Allison Cacciatore		13 JAN 2011
HSE*	Bruce Kilby		14 JAN 2011
QPQV	Carl Slutter		14 JAN 2011

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

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.
Part 3 Function RFG01	Changed Criticality Assessment of RFG01 Temperature Control function to Quality Critical. Function is required to achieve or maintain a critical cGMP environment.
	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 ± 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 4th function "The system controller shall provide audible alarms". Per URS D004189 no requirement for audible alarms
Part 4 Function RFG01 Page 5	Added to 5th and 6th functions "and Fire Alarm System".
Part 4 Function RFG01 Page 6	Added 2nd 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 3rd 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 ± 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."

Part 3: FCCA – Functional Assessment

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Function Description	Functional Assessment (Yes / No) 1	2	3	4	Quality Critical (C-TP)	Quality Non-Critical (NC-TP)	HSE Critical (NC-TP)	Rationale and Comments
RFG01	Temperature Control	N	Y	N	N	☒	☐	☐	Function requires that the temperature of cold room chamber is automatically maintained between 2 to 5°C for the bulk product storage conditions. Function requires local indication of the Temperature and Alarms listing displayed, as applicable. Function requires transmission of the critical alarm data to B6 Galaxy System and Fire Alarm System. Function specifies that 'As Left' accuracy of temperature control loop must be ± 0.5°C of NIST traceable calibration standard.
RFG02	Temperature Recording	N	N	Y	N	☒	☐	☐	Function requires that the Cold Room temperature is continuously recorded on a 7 day circular chart for a period of 24 hours per day. 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	N	N	N	N	☒	☐	☐	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	N	N	N	N	☐	☒	☐	Function requires that access levels are properly protected using passwords to access process set up parameters.
RFG05	Entrance Door Security	N	N	N	N	☐	☒	☐	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	N	N	N	N	☐	☒	☐	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	N	N	N	Y	☐	☐	☒	Function specifies that the Internal Lighting Level is greater than or equal to 5 ft-candles at 35 inches above the finished floor.
RFG08	Internal Noise Level	N	N	N	Y	☐	☐	☒	Function specifies that the Permissible Exposure Limit (PEL) for Occupational Noise Exposure is < 85 dBA as an 8-hr TWA.

Part 3: FCCA – Functional Assessment Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Function Description	Functional Assessment (Yes / No) 1	2	3	4	Quality Critical (C-TP)	Quality Non-Critical (NC-TP)	HSE Critical (NC-TP)	Rationale and Comments
RFG09	Redundancy	N	N	N	N	☐	☒	☐	Function to maximize equipment and components useful life by providing duplicated equipment with a Redundant operating sequence.
RFG10	Maintainability	N	N	N	N	☐	☒	☐	Function will only have an impact on maintenance operations.
RFG11	HSE	N	N	N	N	☐	☐	☒	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: FCCA – Functional Test Plan

System Name	Cold Room 3 in Building 72		System ID Number	072RFG03			
Function ID	**Description**	**Test Case**	**Acceptance Criteria**	**Acceptance Criteria Source**	**C-TP or NC-TP**	**FT[1] or IFT**	**FAT[2] or SAT**
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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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					
RFG01	The system control shall send an alarm to Galaxy System[3] 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[3] Systems when Cold Room door is open longer than set time.	Refer to Part 7 – Alarms and Interlocks					

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.

Part 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT[1] or IFT	FAT[2] or SAT
RFG01	The system control shall send an alarm to Labwatch System[3] when Compressor 1A or 1B fault is detected.	Refer to Part 7 – Alarms and Interlocks					
RFG01	The system control shall send an alarm to Galaxy System[4] when Compressor 1A or 1B fault is detected.	Refer to Part 7 – Alarms and Interlocks					
RFG01	The system control shall send an alarm to Fire Alarm System[4] 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 ± 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 ±0.5°C of NIST traceable calibration standard by reference to calibration certificate.	*Stantec PN: 191000912 Section 13041 GQ_000863*	C-TP ☐ NC-TP ☒	IFT	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 ☐	IFT	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 ☐	IFT	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 ☐	IFT	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).
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

Part 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT[1] or IFT	FAT[2] 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 ☐	IFT	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 ☐ NC-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 ☐ NC-TP ☒	IFT	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 ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03			
Function ID	**Description**	**Test Case**	**Acceptance Criteria**	**Acceptance Criteria Source**	**C-TP or NC-TP**	**FT[1] or IFT**	**FAT[2] 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 ☐ NC-TP ☒	IFT	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: 191000912 Section 13041 21 CFR211.63*	C-TP ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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)

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.			

Part 6: FCCA – Instruments

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Instrument		Instrument Criticality Assessment (Y/N) [1]			IIF Criticality Classification	Normal Operating Range	Rationale and Comments
		Quality		HSE			
P&ID Tag #	Description	1	2	3	4		
072RFG03TIC0101	Temperature Indicating Controller	N	Y	N	Process Critical	1-8°C	The failure of this instrument will have a direct impact on the temperature within Cold Room.
072RFG03TIR0101	Temperature Indicating Chart Recorder	Y	N	N	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] Instrument Criticality Classifications

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. **IIF 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).

Part 7: FCCA – Alarms and Interlocks

System Name	Cold Room 3 in Building 72						System ID Number	072RFG03	
Alarm	Alarm on Critical Control or Critical Primary Data? (Y/N)		HSE Critical (Y/N)	Quality Critical	Quality Non-Critical	HSE Critical	Test Case	Acceptance Criteria	Test Ref
				C-TP	NC-TP				
ID # / Description	1	2	3	4	5	6			
N/A – Cold Room High Temperature	Y	N	N	☒	☐	☐	Verify alarm functions as expected.	The system issues an alarm when the Cold Room temperature is higher than high alarm set point. The alarm is received at Galaxy[1] System in B6 Security Operations Center (SOC).	A1
N/A – Cold Room Low Temperature	Y	N	N	☒	☐	☐	Verify alarm functions as expected.	The system issues an alarm when the Cold Room temperature is lower than low alarm set point. The alarm is received at Galaxy System in B6 SOC.	A2
N/A – Cold Room Door Open	N	N	N	☐	☒	☐	Verify alarm functions as expected.	The system issues an alarm when the Cold Room door is open longer than set time. The alarm is received at Galaxy System in B6 SOC.	A3
N/A – Cold Room 3 Compressor 1A or 1B Fault	N	N	N	☐	☒	☐	Verify alarm functions as expected.	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.	A4

Alarm Criticality Classifications

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.

[1]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.

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03		
Document Identification	Required? (Yes / No)	Mechanical Completion			
		Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	Required for C-TP
P&IDs	☒ Y ☐ N	100%			--
Air Flow / Air Balancing Diagram	☐ Y ☒ N	100%			--
Isometric Drawings (3D)	☐ Y ☒ N	100%			--
Equipment & Component Detail Drawings	☐ Y ☒ N	Spot Check			--
Control Panel Drawings	☐ Y ☒ N	Spot Check			--
Control System Wiring Diagrams	☒ Y ☐ N	Spot Check			--
Control System Architecture Drawings	☐ Y ☒ N	100%		(1)	--
Network Architecture Diagrams	☐ Y ☒ N	100%		N/A	--
Pneumatic Distribution Diagrams	☐ Y ☒ N	Spot Check		23MAR2011	--
Loop or Segment Drawings	☐ Y ☒ N	Spot Check			--
Electrical Panel Drawings	☐ Y ☒ N	Spot Check			--
Electrical Wiring Diagrams & Schematics	☒ Y ☐ N	Spot Check			--
*Material of Construction Certificates	☐ Y ☒ N	100%			--
Instrument Cut Sheets	☒ Y ☐ N	Spot Check			--
Mechanical Component Cut Sheets	☒ Y ☐ N	Spot Check			--
Gasket and O-Ring Spec Sheets	☐ Y ☒ N	Spot Check			--
*Lubricant List	☐ Y ☒ N	100%			--

* Required for Direct Impact Systems Only

(1) THIS PART OF THE FCCA WAS DOCUMENTED AND VERIFIED IN THE PREVIOUS REVISION OF THE FCCA. SEE PREVIOUS FCCA ATTACHED. 23MAR2011

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03		
Document Identification	**Required? (Yes / No)**	**Mechanical Completion**			
		Audit Level	**Storage Location (TOP, FAT, SAT)**	**Verified by Initials /Date**	**Required for C-TP**
*Weld Procedure Qualification	☐ Y ☒ N	100%			--
*Weld Procedure Specifications	☐ Y ☒ N	100%			--
*Welding Operator Qualification	☐ Y ☒ N	100%			--
*Weld Maps	☐ Y ☒ N	100%			--
*Weld Logs	☐ Y ☒ N	100%			--
*Weld Filler Material Datasheets	☐ Y ☒ N	100%			--
*Weld Purge Gas Certificates of Analysis	☐ Y ☒ N	100%			--
*Cleaning and Passivation Records	☐ Y ☒ N	100%		N/A	--
*Electro polishing Certificate	☐ Y ☒ N	100%		23 MAR 2011	--
*Surface Finish Test Report	☐ Y ☒ N	100%			--
Pressure Vessel Code Certificate	☐ Y ☒ N	100%			--
Relief Device Certificates	☐ Y ☒ N	100%			--
Hydrostatic Test Certificate	☐ Y ☒ N	100%			--
Pneumatic Pressure Test Certificate	☐ Y ☒ N	100%			--
*Drainage Test Records	☐ Y ☒ N	100%			--
*Slope Verification Records	☐ Y ☒ N	100%			--

* Required for Direct Impact Systems Only

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03		
Document Identification	Required? (Yes / No)	Mechanical Completion			
		Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	Required for C-TP
Alarm and Interlock List	☒ Y ☐ N	Spot Check			--
Sequence of Operations	☒ Y ☐ N	Spot Check			--
Ladder Logic Diagram	☐ Y ☒ N	Spot Check			--
Configuration Data Sheets	☐ Y ☒ N	100%		N/A	--
Software Configuration Reports	☐ Y ☒ N	100%		N/A 23 MAR 2011	--
Software Unit/Integration Test Results	☐ Y ☒ N	100%			--
Installation, Operation and Maintenance Manuals (O&M)	☒ Y ☐ N	100%			--
Refrigerant Data Sheet	☒ Y ☐ N	100%			--
Wall and Ceiling Material Data Sheet	☒ Y ☐ N	100%			--

* Required for Direct Impact Systems Only

A005120
7172-233-00

Part 1: FCCA – System Identification

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 Product Quality (check one)		**Impact on HSE?** (Yes or No)	
Direct Impact: ☒	**Indirect Impact / No Impact:** ☐	**Yes:** ☐	**No:** ☒

Department	Printed Name	Signature	Date
System Owner	Dean Wehr	Dean D Wehr	09 oct 2010
End User	Joan Corcia		04 OCT 2010
EIT C&Q	Mike Polansky		04 Oct 2010
EIT	Allison Cacciatore	Allison Cacciatore	04 Oct 2010
HSE*	Bruce Kilby	for Bruce Kilby	04 OCT 2010
QPQV	Carl Slutter		04 OCT 2010

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

2. Part 3: FCCA – Functional Assessment

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Function Description	Functional Assessment (Yes / No) 1	2	3	4	Quality Critical (C-TP)	Quality Non-Critical (NC-TP)	HSE Critical (NC-TP)	Rationale and Comments
RFG01	Temperature Control	N	N	N	N	☐	☒	☐	Function requires that the temperature of cold room chamber is automatically maintained between 2 to 5°C for the bulk product storage conditions. Function requires local indication of the Temperature and Alarms with audible 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.
RFG02	Temperature Recording	N	N	Y	N	☒	☐	☐	Function requires that the Cold Room temperature is continuously recorded on a 7 day circular chart for a period of 24 hours per day. 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.
RFG03	Temperature Recovery	N	N	N	N	☒	☐	☐	Function requires that the Cold Room temperature recovers to operating range within the specified time when door is open during product loading or unloading.
RFG04	Controller Access Security	N	N	N	N	☐	☒	☐	Function requires that access levels are properly protected using passwords to access process set up parameters.
RFG05	Entrance Door Security	N	N	N	N	☐	☒	☐	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	N	N	N	N	☐	☒	☐	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	N	N	N	Y	☐	☐	☒	Function specifies that the Internal Lighting Level is greater than or equal to 5 ft-candles at 36 inches above the finished floor.
RFG08	Internal Noise Level	N	N	N	Y	☐	☐	☒	Function specifies that the Permissible Exposure Limit (PEL) for Occupational Noise Exposure is < 85 dBA as an 8-hr TWA.

Part 3: FCCA – Functional Assessment Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Function ID	Function Description	Functional Assessment (Yes / No) 1	2	3	4	Quality Critical (C-TP)	Quality Non-Critical (NC-TP)	HSE Critical (NC-TP)	Rationale and Comments
RFG09	Redundancy	N	N	N	N	☐	☒	☐	Function to maximize equipment and components useful life by providing duplicated equipment with a Lead/Lag operating sequence.
RFG10	Maintainability	N	N	N	N	☐	☒	☐	Function will only have an impact on maintenance operations.
RFG11	HSE	N	N	N	N	☐	☐	☒	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: FCCA – Functional Test Plan

System Name	Cold Room 3 in Building 72		System ID Number	072RFG03			
Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT[1] or IFT	FAT[2] or SAT
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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	SAT
RFG01	The system controller shall provide audible alarms.	Verify that system controller provides audible alarms.	Control display function as expected.	*Stantec PN: 191000912 Section 13041*	C-TP ☐ NC-TP ☒	IFT	SAT
RFG01	The system control shall send an alarm to Galaxy[3] System when high temperature is detected in the Cold Room.	Refer to Part 7 – Alarms and Interlocks					
RFG01	The system control shall send an alarm to Galaxy 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[3] Systems when Cold Room door is open longer than set time.	Refer to Part 7 – Alarms and Interlocks					

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.

Part 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72		System ID Number	072RFG03			
Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT[1] or IFT	FAT[2] 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					
RFG01	The system control accuracy between the temperature set point and the true temperature resulting from the setting shall be plus or minus 0.5°C.	Verify that temperature controller accuracy is plus or minus 0.5°C.	Controller accuracy is plus or minus 0.5°C.	*Stantec PN: 191000912 Section 13041 GQ_000863*	C-TP ☐ NC-TP ☒	IFT	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 ☐	IFT	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 ☐	IFT	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 ☐	IFT	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 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03			
Function ID	**Description**	**Test Case**	**Acceptance Criteria**	**Acceptance Criteria Source**	**C-TP or NC-TP**	**FT[1] or IFT**	**FAT[2] or 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 ☐	IFT	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 ☐ NC-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 ☐ NC-TP ☒	IFT	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 ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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).

A005120
7172-233-00

Part 4: FCCA – Functional Test Plan Continued

System Name	Cold Room 3 in Building 72		System ID Number	072RFG03			
Function ID	Description	Test Case	Acceptance Criteria	Acceptance Criteria Source	C-TP or NC-TP	FT[1] or IFT	FAT[2] or 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 ☐ NC-TP ☒	IFT	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: 191000912 Section 13041 21 CFR211.63*	C-TP ☐ NC-TP ☒	IFT	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 ☐ NC-TP ☒	IFT	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)

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.

Part 6: FCCA – Instruments

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03

Instrument		Instrument Criticality Assessment (Y/N)[1]			IIF Criticality Classification	Normal Operating Range	Rationale and Comments
		Quality		HSE			
P&ID Tag #	Description	1	2	3	4		
072RFG03TIC0301	Temperature Indicating Controller	N	Y	N	Process Critical	1-8°C	The failure of this instrument will have a direct impact on the temperature within Cold Room.
072RGF03TIR0301	Temperature Indicating Chart Recorder	Y	N	N	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] Instrument Criticality Classifications

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. **IIF 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).

Part 7: FCCA – Alarms and Interlocks

System Name		Cold Room 3 in Building 72						System ID Number	072RFG03	
Alarm		Alarm on Critical Control or Critical Primary Data? (Y/N)		HSE Critical (Y/N)	Quality Critical	Quality Non-Critical	HSE Critical	Test Case	Acceptance Criteria	Test Ref
					C-TP	NC-TP				
ID #	Description	1	2	3	4	5	6			
N/A	Cold Room High Temperature	Y	N	N	☒	☐	☐	Verify alarm functions as expected.	The system issues an alarm when the Cold Room 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).	A1
N/A	Cold Room Low Temperature	Y	N	N	☒	☐	☐	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
N/A	Cold Room Door Open	N	N	N	☐	☒	☐	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 System in B6 SOC.	A3
N/A	Cold Room 1 Compressor 1A or 1B Fault	N	N	N	☐	☒	☐	Verify alarm functions as expected.	The system issues an alarm when the compressor does 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

[1]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.

Part 7: FCCA – Alarms and Interlocks Continued

System Name		Cold Room 3 in Building 72						System ID Number		072RFG03	
Alarm		Alarm on Critical Control or Critical Primary Data? (Y/N)		HSE Critical (Y/N)	Quality Critical	Quality Non-Critical	HSE Critical	Test Case	Acceptance Criteria		Test Ref
					C-TP	NC-TP					
ID #	Description	1	2	3	4	5	6				
Alarm Criticality Classifications											
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.											

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03		
Document Identification	Required? (Yes / No)	Mechanical Completion			Required for C-TP
		Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	
P&IDs	☒ Y ☐ N	100%	SAT-B72-003 ATTACHMENT #2	DR 04 OCT 2010	X
Air Flow / Air Balancing Diagram	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Isometric Drawings (3D)	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Equipment & Component Detail Drawings	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Control Panel Drawings	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Control System Wiring Diagrams	☒ Y ☐ N	Spot Check	SAT-B72-003 ATTACHMENT #3	DR 04 OCT 2010	--
Control System Architecture Drawings	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Network Architecture Diagrams	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Pneumatic Distribution Diagrams	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Loop or Segment Drawings	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Electrical Panel Drawings	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Electrical Wiring Diagrams & Schematics	☒ Y ☐ N	Spot Check	SAT-B72-003 ATTACHMENT #5	DR 04 OCT 2010	--
*Material of Construction Certificates	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Instrument Cut Sheets	☒ Y ☐ N	Spot Check	SAT-B72-003 ATTACHMENT #7,8	DR 04 OCT 2010	--
Mechanical Component Cut Sheets	☒ Y ☐ N	Spot Check	VOLUME 2-VTOP TABE	DR 04 OCT 2010	--
Gasket and O-Ring Spec Sheets	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
*Lubricant List	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--

* Required for Direct Impact Systems Only

A005120
7172-233-00

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG03		
Document Identification	Required? (Yes / No)	Mechanical Completion			Required for C-TP
		Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	
*Weld Procedure Qualification	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Weld Procedure Specifications	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Welding Operator Qualification	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Weld Maps	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Weld Logs	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Weld Filler Material Datasheets	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Weld Purge Gas Certificates of Analysis	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Cleaning and Passivation Records	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Electro polishing Certificate	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Surface Finish Test Report	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Pressure Vessel Code Certificate	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Relief Device Certificates	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Hydrostatic Test Certificate	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
Pneumatic Pressure Test Certificate	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Drainage Test Records	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--
*Slope Verification Records	☐ Y ☒ N	100%	N/A	DR 04 OCT 2010	--

* Required for Direct Impact Systems Only

A005120
7172-233-00

Part 8: FCCA – Document Verification

System Name	Cold Room 3 in Building 72	System ID Number	072RFG032		
Document Identification	Required? (Yes / No)	Mechanical Completion			Required for C-TP
		Audit Level	Storage Location (TOP, FAT, SAT)	Verified by Initials /Date	
Alarm and Interlock List	☒ Y ☐ N	Spot Check	VOLUME 2-VTOP TAB A	DR 04 OCT 2010	--
Sequence of Operations	☒ Y ☐ N	Spot Check	VOLUME 2-VTOP TAB A	DR 04 OCT 2010	--
Ladder Logic Diagram	☐ Y ☒ N	Spot Check	N/A	DR 04 OCT 2010	--
Configuration Data Sheets	☐ Y ☒ N	100%	N/A	DR04OCT2010	--
Software Configuration Reports	☐ Y ☒ N	100%	N/A	DR04OCT 2010	--
Software Unit/Integration Test Results	☐ Y ☒ N	100%	N/A	DR04OCT2010	--
Installation, Operation and Maintenance Manuals (O&M)	☒ Y ☐ N	100%	VOLUME 2-VTOP TAB E	DR04OCT2010	--
Refrigerant Data Sheet	☒ Y ☐ N	100%	VOLUME 3-CTOP TAB B	DR04OCT2010	--
Wall and Ceiling Material Data Sheet	☒ Y ☐ N	100%	VOLUME 3-CTOP TAB B	DR04OCT2010	--

* Required for Direct Impact Systems Only