Documentation #: OQ Serial NO. 9999999

Protocol Name:	Operational Qualification Protocol
Protocol Number:	FRM630-03.02
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019 :
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019 :
Document Date:	05/06/2019
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
OPTIONS on Sterilizer:	
Fast Cooling:	COOLING50xxELV-D
Super Fast Cooling (FAN support):	FAN-50
Stand-alone Air compressor	COM-050 Serial number: 888888
Vacuum System:	VAC-38/50
Bio Hazard Filter system:	BHF-B
Automatic water filling system:	Included in model
Steam Generator:	N/a
Printer:	THE002-0080
Independent Recording:	IAR-001
Remote PC Reporting Software:	ADD222-0461

PROTOCOL APPROVALS

Protocol Name:	Operational Qualification Protocol
Protocol Number:	FRM630-03.02
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
OQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Management			

VALIDATION FINAL REPORT APPROVALS

Protocol Name:	Operational Qualification Protocol
Protocol Number:	FRM630-03.02
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
OQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Manager			

TABLE OF CONTENTS

1.0 OBJECTIVE

A. To verify that the autoclave is operating correctly and will consistently perform the intended sterilization process.
B. All sensors and instruments permanently installed with the equipment will be functioning properly and are calibrated (if required). Utility connections are correctly installed and fully operational. Operational testing of the installed autoclave will be carried out in coordination with the autoclave vendor. This OQ will ensure that the equipment is operating as designed.
C. The equipment and system will be ready for Performance Qualification.

2.0 DESCRIPTION

A. This protocol is to be executed prior to PQ.
B. Some subsections of the protocol may be repeated following 'significant' changes in the process or operation according to the Change Control Protocol.
C. The qualification study will establish sterilization exposure time/temperature conditions adequate to assure a probability of non-sterility not greater than 10^{-6} for each approved loading configuration.

3.0 PRODUCT DESCRIPTION

Equipment Identification: Tuttnauer Steam Sterilizer

Contract No:	
Customer:	End User Company Name
Location:	
Area:	
Item No:	
Item Name:	
Model:	5075ELV-D
Serial Number:	9999999
Software Version:	9.9.9
Software Revision No:	.9
Software Revision Date:	x-xx-yyyy

Autoclave Model **5075ELV-D** is a sterilizer designed especially for Laboratory Use.

For further information and details please see the Operation & Maintenance Manual number:

MAN999-9999999EN Revision: **Rev X**

4.0 REFERENCES

The following documents are the references for the facility validation.

A. Standard Operating Procedure System:
B. Calibration Procedure System:
C. Validation Protocol:
D. Autoclave Manual and adequate rev.:

5.0 SCOPE

The scope of the Installation Qualification is limited to the equipment listed in the table below.

Equipment	
AUTOCLAVE:	5075ELV-D Sn: 9999999

6.0 RESPONSIBILITIES

The following roles have been assigned and responsibilities assumed:

A. Advisor (End User Company Name)

1. Review and Approve Validation documents.
2. Provide guidance for the parties involved in the validation effort.

B. Validation Team (Tuttnauer Distributor)

1. Review and Approve Validation document.
2. Execute Validation including Qualification of the systems and subsystems.
3. Provide coordination for the parties involved in the validation effort.
4. Calibration of instrumentation.

C. QA/QC (Tuttnauer Distributor together with End User Company Name)

1. Review and Approve Validation documents.
2. Provide GMP and regulatory guidance.
3. Test samples generated from execution of validation protocols.

7.0 CALIBRATION OF MEASURING INSTRUMENTS

All test instrumentation shall be calibrated prior to the execution of this protocol. Reference standards and calibration instruments themselves shall be calibrated and traceable to national standards.

All calibrations shall be performed according to an approved SOP for Calibration of measuring devices by an authorized contractor.

Complete documentation to support calibration shall be attached to this protocol prior to final sign off. This includes test reports and calibration certificates of the measuring instruments used during the Operational Qualification

Instrument List for Calibration and their calibration status before the test

Item ID #	Instrument Description	Calibration Document Ref. #	(Re)Calibration Date (dd/mm/yy)

8.0 SAFETY TESTING PROCEDURES

Complete the following procedure(s) as described in the safety testing procedure prior to Operational Qualification.
Use the below mentioned document for safety testing.

Autoclave Model: 5075ELV-D

Safety testing manual number: **MOD777-77777EN** Revision: **Rev Z**

Safety test Performed? (Y/N): _____ _____ _____
Signature **Date**

Safety test Satisfactorily? (Y/N): _____ _____ _____
Signature **Date**

9.0 OPERATIONAL QUALIFICATION

Note: The Operational Qualification will be performed after the Installation Qualification has been completed.

The Operational Qualification (OQ) is a testing process which evaluates the Autoclave in Final Testing Department. Adjustment of Control is confirmed during this phase of testing and performance trials are conducted to verify that the Autoclave operates in accordance with design specifications. During the OQ, data is collected concerning critical processing parameters which could affect operation.

9.1 Alarm Checkout

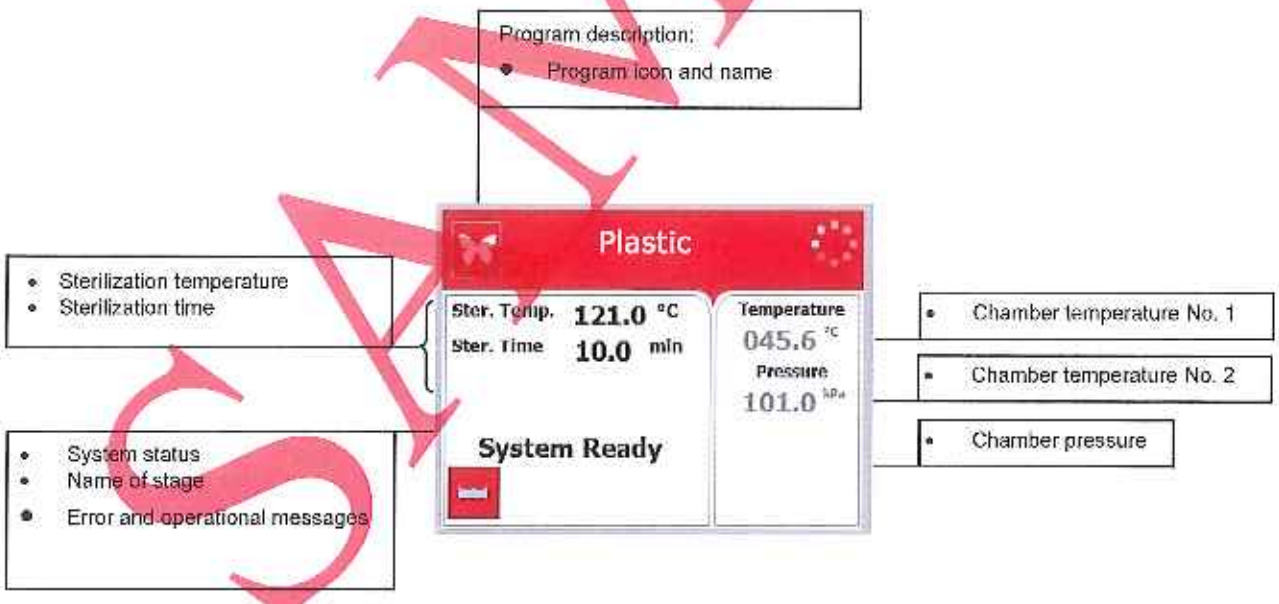
System alarms will be tested to determine if the desired action and response are achieved during out of limit sequences. Where possible, alarms will be challenged by testing the alarm limit in response to actual conditions created in the system. Set points will be challenged to determine alarm function where alarm limits and set points are

Equipment/System Item No. _____

Equipment/System Description: _____

Display

The LCD display is used to display the current status of the autoclave, Operational Messages and Error Messages.



Keypad

The keypad consists of three keys as described below:

UP key

This key has the following functions:

- In the menu directories:
  - This key enables the operator to browse through the cycles.
- In the directories available:
  - When the cursor is blinking on a number, the **UP** ▲ key increases its value.
  - When the cursor is blinking on a menu selection, the **UP** ▲ key allows browsing backward through the menu.
  - When adjusting a parameter and the cursor is blinking on "SET" or "EXIT" the **UP** ▲ key activates that procedure."

DOWN key

This key has the following functions:

- In the menu directories:
  - This key enables the operator to browse through the cycles.
- In the directories available:
  - When the cursor is blinking on a number, the **DOWN** ▼ key decreases its value.
  - When the cursor is blinking on menu selection, the **DOWN** ▼ key allows browsing forward through the menu.
  - When adjusting a parameter and the cursor is blinking on "SET" or "EXIT" the **DOWN** ▼ key activates that procedure.

START/STOP key

This key has the following functions:

- In the main screen:
  - Starts the process when the required program was chosen.
  - Stops the current process.
  - Cancels the ERROR message displayed on the screen and opens the electric door lock.
- In the menu directories:
  - When the cursor is blinking on a number, the **START/STOP** ⏻ key enables moving to the next position.
  - When the cursor is blinking on a menu selection, the **START/STOP** ⏻ key activates that selection.

Displayed Error Messages / Symbols

The failures are divided into two categories.

a. Failure that occur before completing the sterilization stage, which in this case will leave the load unsterilized
b. Failure that occur after completing the sterilization stage, which in this case will leave the load sterilized

Displayed operational messages / Symbols

Message / Symbol Name	Message / Symbol Description	Required Action
	This symbol is displayed when the door is open.	Close the door.
Door is open (during stand by)	This message is displayed when the door is opened: In standby - if **START/STOP** is preset.	Close the door to perform a new cycle.
Cycle Ended	This message is displayed when the cycle ended successfully.	Press **START/STOP** in order to perform a new cycle.
Test Ended	This message is displayed when the test ended.	Press **START/STOP** in order to perform a new test
	This symbol is displayed when Cycle by Clock mode is performed.	Enter the Admin menu as described in this manual to change the time or to cancel this option.
Cycle by clock	This message is displayed if the user presses **START/STOP** key while the "cycle by clock" mode is active.	Enter the Admin menu as described in this manual to change the time or to cancel this option.
Atmospheric pressure not set	This message id displayed in order to set the atmosphere pressure by opening the door for 5 minutes.	Open the door for 5 minutes in order to set the Atmospheric pressure.
Critical settings have been updated, Please restart machine in order for changes to be updated	If a change of the autoclave setting was made, a restart operation is required.	Restart the autoclave in order for changes to be updated.
	This message is displayed if the electrode in the chamber senses water.	Perform a new cycle to drain the chamber.

9.2 Screens

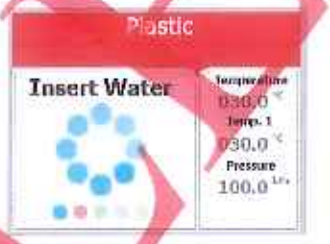
9.2.1 Screens following a completely successful cycle – "Cycle Ended"

Indication of possible Cycle Phases (these can differ for each program)!!

1. System Ready

2. Starting

3. Insert Water



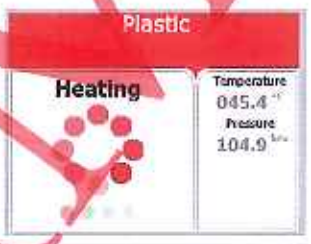
4. Steam Flush

5. Pulse H

6. Pulse L

7. Keep Heat *

8. Heat



9. Sterilization

10. Exhaust

12. Ending

13. Cycle Ended

* Display can be activated only by an authorized person.

In order to open the door press **"START/STOP"** key

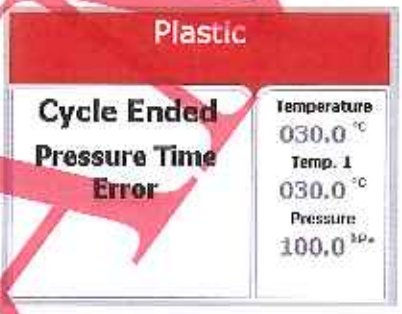
9.2.2 Screens following aborted cycles after complete sterilization stage

The sterilization phase ended successfully – cycle ended and the reason of failure is displayed
For example the next two scenarios:

Canceled by user after complete sterilization stage

The cycle ended successfully, the reason for aborted cycle is displayed.

Pressure Time Error Failure occurrence after complete sterilization stage
The cycle ended successfully, the reason of failure is displayed.



9.2.3 Screens following a failed cycle

In this case, the display becomes yellow, a warning sign ⚠ and the reason of failure will be displayed.

9.2.4 Failure according to Pressure Time Error

9.2.5 Failure according to Cancellation by user before complete sterilization stage

When "Cycle Failed" appears on the screen, the user shall press **"START/STOP"** key in order to delete the "Cycle Failed" message

An example for all displayed warnings according to Cycle Failed:

9.2.6 Alarm List (Yellow Marked alarms are for Laboratory sterilizers only !!)

ALARM ID #	DESCRIPTION/ LOC	SET POINT		ACCEPT/ REJECT
Low Temp.	In the Sterilization stage, the temperature drops below the sterilization temperature for more than 1 second.	Sterilization Temperature		
High Temp	In the Sterilization stage, the temperature exceeds the Sterilization Temperature for more than Sterilization Temperature Range parameter value.	Sterilization Temperature, Sterilization temperature Range.		
High Temp. (Ending)	In the Ending stage, the chamber temperature does not go below the temperature defined in parameter End Temperature for the time, defined in parameter Normal Temperature Timeout	End Temperature, Normal Temperature Timeout		
High Temp. (Cooling)	The system cannot reach the required temperature, in the cooling stage, within the preset time.			
Heat Time Error	In the Heat stage, chamber temperature can not reach the Sterilization Temperature after the time defined in parameter Heat Time Error	Sterilization Temperature, Heat Time Error		
Low Pressure	In Sterilization stage, the chamber pressure goes below the value of Sterilization Pressure. for 2 seconds.	sterilization pressure (134°C = 304 kPa, 121°C = 205 kPa)		
Low Pressure (Cooling)	The Chamber Pressure does not reach the preset pressure before initiating the cooling stage.			
High Pressure	In Sterilization stage, the chamber pressure goes above the Sterilization Pressure, plus the Sterilization Pressure Range value , for 2 seconds in the sterilization stage.	Chamber Pressure raises 4.2 psi-29 kPa above sterilization pressure (134°C = 304 kPa, 121°C = 205 kPa)		

ALARM ID #	DESCRIPTION/ LOC	SET POINT		ACCEPT/ REJECT
High Pressure (Ending)	In the ending stage, the system cannot reach the atmospheric pressure ± 10kPa.			
High Pressure (Exhaust)	The system cannot reach preset pressure within 10 minutes from the beginning of the exhaust stage.			
Pressure Time Error	Pulse pressure has not been achieved within the time defined in Pressure Time Error	Pressure Time Error		
Compressed air supply error (ELVC only)	Compressed air supply malfunction.			
Periodical check time exceeded - Please call for service	The Periodical Maintenance Time has passed.			
Cycle counter exceeded - Please call for service	Number of cycles, since the last periodical maintenance, exceeded the preset number as defined by Cycle Counter parameter.			
No Water	If the system has detected no water in the chamber within the time defined in No Water, a No Water error will be displayed and the cycle will fail.	No Water parameter defines the maximum time to wait for water to be detected in the chamber in insert water stage		
Analog Input Error	This message is displayed when any temperature sensor or pressure sensor is disconnected or out of range.			
Chamber temperature not in range	Chamber temperature is outside the normal range.			

ALARM ID #	DESCRIPTION/ LOC	SET POINT		ACCEPT/ REJECT
Chamber pressure not in range	Chamber pressure is outside the normal range.			
I/O Card Failed	The I/O card (connected to the main through RS232 connector) is not responding.			
I/O card is not connected	1. Disconnection between I/O board and Main board. 2. I/O card is faulty (both while the cycle is running or not).			
Open door icon is displayed after closing the door.	The microswitch is faulty.			
Power down	Power failure during the cycle.			
Door is open	The door switch indicates that the door is open.			

Comments: _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

9.3 Control Panel Checkout

Verify the function of the switches and indicator lights on the control panels for the Autoclave. Using attachment record the tag number and label identifying the switches and indicator lights. Indicate the function of each (e.g. ON/OFF) and verify each function.

Equipment/System Item No.: _____

Equipment/System DESC : _____

Control Panel I.D.#: _____

TAG #/ DESCRIPTION	FUNCTION	VERIFIED	
		YES	NO
Up key	Change programs (door must be open) Open door for (38xx models)	☐	☐
Down key	Change programs (door must be open)	☐	☐
Start/stop key	Start and stop cycle	☐	☐
Display	Display the cycle name stage of the cycle and indicate current values of - Chamber Pressure -.Chamber Temperature - Reference Temperature (Liquid)	☐	☐

Comments: _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

9.4 Sequence of Operation

To prove that the system operates as defined in the system sequence of operation document and user requirements. Alternately, provide vendor-generated documentation that properly demonstrates and documents operational sequences. Test will be developed to run equipment under specified conditions and system response will be verified. These shall include: sequences for all controllers, on/off switches, toggle switches, and emergency stop pushbutton.

Equipment/System Item No.: _____

Equipment/System Description: _____

Vendor Operation Manual No.: MAN999-9999999EN Revision: Rev X

System Operation in the Sequence of Operation Document and User Manual:

1. Cycle Name: _____

   Sterilization Temperature: _____ Sterilization Time: _____

   Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

2. Cycle Name: _____

   Sterilization Temperature: _____ Sterilization Time: _____

   Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

3. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

4. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

5. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

6. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

7. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

8. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

9. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

10. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

11. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

12. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

13. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

14. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

15. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

16. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

17. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

18. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

19. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

20. Cycle Name: _____

Sterilization Temperature: _____ Sterilization Time: _____

Dry time: _____

Satisfactory ☐ Unsatisfactory ☐

Comments: _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.1A
DOCUMENTATION

Equipment/System Item No.: _____

Equipment/System Description: _____

DOCUMENTS

Document	Specified	Available
Title:	O & M Manual	☐
Number:	MAN999-9999999EN	☐
Revision No.:	Rev X	☐
Storage Location of Document:		
Title:	Technical Manual	☐
Number:	MAN888-8888888EN	☐
Revision No.:	Rev Y	☐
Storage Location of Document:		
Title:	Safety Testing Manual	☐
Number:	MOD777-77777EN	☐
Revision No.:	Rev Z	☐
Storage Location of Document:		
Title:		☐
Number:		☐
Revision No. / Issue Date:		☐
Storage Location of Document:		

Comments: _____

_____

_____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2A
OPERATIONAL QUALIFICATION SUMMERY

Equipment/System Item No.: _____

Equipment/System Description: _____

Discrepancy/variation:

_____

_____

_____

_____

_____

_____

_____

_____

Resolution: _____

_____

_____

Satisfactorily completed?: (Y/N) _____ _____ _____

Signature Date

Discrepancy/variation _____

_____

_____

Resolution: _____

_____

_____

Satisfactorily completed?: (Y/N) _____ _____ _____

Signature Date

SUMMARY: _____

_____

_____

All items in the Operational Qualification section of this protocol have been satisfactorily completed and all variations or discrepancies satisfactorily resolved. Therefore, this system is ready for Performance Qualification.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.3A
COMMENT / ACTION ITEMS

Equipment/System Item No.: _____

Equipment/System Description: _____

This attachment contains a listing of all issue, deviations, and exceptions that were recorded during protocol execution. A listing of all items is included below, and Comment / Action item forms are attached. This comment form summarizes those items as well as any corrective actions taken or responsive justifications.

Comment #	Who	Date Added	Follow Up Required (Yes/No)	Signature	Date Follow Up Completed
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.3B
COMMENT / ACTION ITEM FORM

Equipment/System Item No.: _____

Equipment/System Description: _____

Comment: _____

Response/Corrective Action/Justification: _____

Follow-up Required: (Yes/No) _____ **Requested by:** _____

Explanation of Follow-up: _____

Completed Date: _____ **Signature:** _____

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____