

# Work Instructions

## Operation and Cleaning of Isolator Contained Tray Dryer/Filters

PRD WI 1155km912

*Leader Guide*

Operation and Cleaning of Isolator Contained Tray Dryer/Filters

**[Originator]**

## Contents

INTRODUCTION.....	3
INSTRUCTIONS.....	4

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 3 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b> Introduction					Originator Originator

## ***Introduction***

**Purpose:** Briefly explain why the SOP is needed and what the SOP is intended to accomplish.

**Purpose**                      The purpose of this operating instruction is to provide guidelines for the operation of the Portable Isolator Tray Dryer for use in the Process Scale-Up Facilities in New Brunswick, NJ

**Scope:** Define who is affected by the document. If applicable, also detail activities or roles that are outside the scope of this document. State what departments and locations the procedure applies to.

**Scope**                      This procedure applies specifically to the operation of the portable isolator tray dryers, 81-I-100, -101, and -102 and their associated operator interface and instrumentation

**General Requirements**                      Personnel using this equipment must be familiar with the pertinent SOP's or Operating Instructions in the building and room where it is installed.

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 4 of 12
Operation and Cleaning of Isolator Contained Tray Dryer/Filters Instructions					Originator Originator

## Instructions

### Instructions

### Safety

#### Procedure Steps

Step	Action	Pg.
1	Prior to operating ensure the Isolator Tray Dryer has been properly grounded.	4
2	Remove prefilters on chamber HEPA filters and physically ensure the HEPA filters are in place. Prefilters are changed after every campaign. Ensure new prefilter is installed. Chamber HEPA filters are changed as part of the 6 month Preventive Maintenance schedule or sooner if the differential pressure alarms.	4
3	Move the HEPA cartridge filter on the vacuum line to the dryer in the # 2 position to the #1 position. Install a new cartridge filter in the #2 position. The cartridge HEPA in the #1 position is always removed and discarded after every cleaning cycle.	4
4	Ensure new gloves have been installed at the end of the last campaign. Install new gloves if needed.	4
5	A glove port quick repair plug must be available in the room.	4

#### Step 1.

Prior to operating ensure the Isolator Tray Dryer has been properly grounded.

#### Step 2.

Remove prefilters on chamber HEPA filters and physically ensure the HEPA filters are in place. Prefilters are changed after every campaign. Ensure new prefilter is installed. Chamber HEPA filters are changed as part of the 6 month Preventive Maintenance schedule or sooner if the differential pressure alarms.

#### Step 3.

Move the HEPA cartridge filter on the vacuum line to the dryer in the # 2 position to the #1 position. Install a new cartridge filter in the #2 position. The cartridge HEPA in the #1 position is always removed and discarded after every cleaning cycle.

#### Step 4.

Ensure new gloves have been installed at the end of the last campaign. Install new gloves if needed.

#### Step 5.

A glove port quick repair plug must be available in the room.

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 5 of 12
Operation and Cleaning of Isolator Contained Tray Dryer/Filters Emergency Procedures					Originator Originator

## Emergency Procedures

### Emergency Procedures

#### Procedure Steps

Step	Action	Pg.
1	Loss of a glove	5
2	High chamber pressure	5
3	High differential pressure	5
4	Loss of Power	5
5	E-Stop	6
6	High oxygen level	6

#### Step 1.

Loss of a glove

If a glove is ruptured the Isolator Tray Dryer will go into an alarm breach condition. The fan will go into maximum output in order for the chamber to maintain a negative pressure relative to the room. If this occurs immediately plug the glove port with the glove port repair plug. After a few seconds the unit will come out of breach mode and return to previous phase. Acknowledge the alarm. The project team personnel will have to determine what action to take (clean, decontaminate, etc) prior to installing a new glove.

#### Step 2.

High chamber pressure

If the PLC goes into alarm on high chamber pressure this means there is a leak or an open nitrogen or air valve preventing the chamber fan from maintaining the negative pressure set-point. If this occurs locate the leak or open valve and seal the chamber.

#### Step 3.

High differential pressure

If the PLC goes into alarm on high differential pressure this means that the Chamber HEPA filters or the prefilter is becoming plugged and needs to be changed. Remove the prefilter and set aside in the chamber (this can be bagged and removed via the RTP port for disposal). Install a new prefilter by bringing it in via the RTP port and placing it in the plastic holder. Push the assembly onto the HEPA filter housing. Check to see if the differential pressure is in the normal range.

#### Step 4.

Loss of Power

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 6 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Emergency Procedures					

If there is a power failure the Isolator closes all automatic valves and is in a sealed state. All manual valves on the filter, slurry line, and nitrogen line should be closed and work stopped until power is restored.

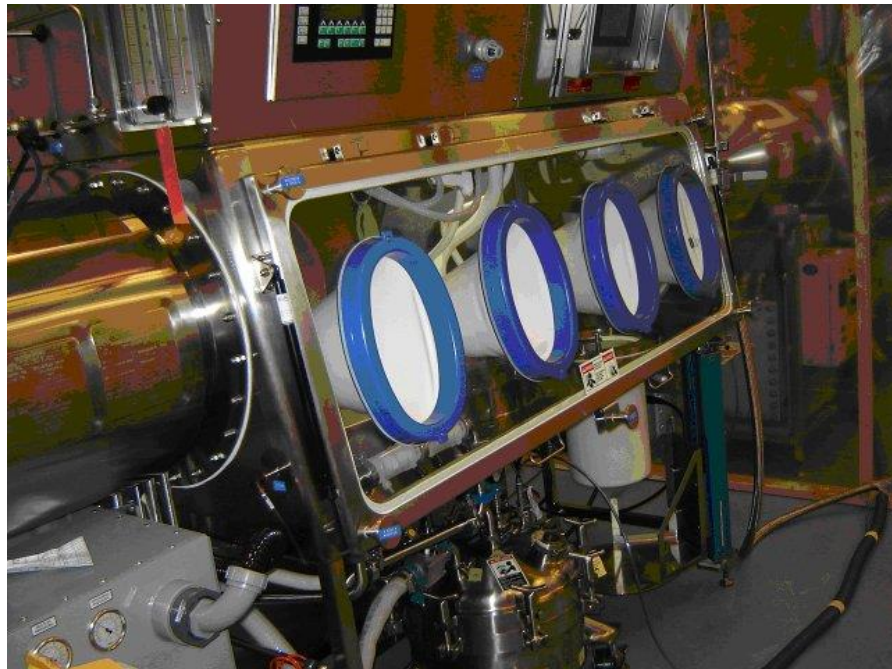
**Step 5.**

E-Stop

If there an emergency in the room which will require an evacuation, the E-Stop button should be pushed. This button is located on the front of the Isolator above the glass glove-port door. This will close all valves, putting the Isolator in a sealed state. It will also cut off power to the blower fan and the vacuum pump. Note that operations of the product filter are completely manual, and valves connected to this filter must be manually closed.

**Step 6.**

High oxygen level



**B81 Isolator Filter Drye**

If there is a high oxygen level alarm, the Isolator either has a leak caused by an open valve or seal problem, or the nitrogen supply to the isolator has been shut off. Restore the nitrogen supply and/or repair the leak to allow the oxygen level to go down to the appropriate level.

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 7 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b> Operations - Pre-Run Procedure					Originator Originator

## Operations - Pre-Run Procedure

### Operations - Pre-Run Procedure

#### Procedure Steps

Step	Action	Pg.
1	In a cleaned Isolator state with the side access door open & system off, verify the following items:	7
2	Load the following items:	8
3	Set up the filter with the required basket & filter media into tank ring.	9
4	Close the filter lid & lock the swing bolts in place. Make connections to the following items in the chamber:	10
5	Make connections to the following items outside the chamber :	11
6	Run a vacuum test on the dryer and filter	11
7	Close the front window and tighten the bolts.	12
8	Start the system and run a "pressure decay" test from the isolator HMI screen.	12

#### Step 1.

In a cleaned Isolator state with the side access door open & system off, verify the following items:



Removing prefilter from Hepa housing

- Gloves with retaining covers are in place

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 8 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Operations - Pre-Run Procedure					

- Millipore filters are in place (quantity 3)
- Remove prefilters covering exhaust and inlet air HEPA filter housings. Visually inspect housing to ensure HEPA filters are in place. Replace prefilters.
- Oven door is open & all six trays are on the appropriate shelves
- RTP Alpha door is secured "closed"



RTP Port with Alpha Door Open to container

- Gloves with retaining covers are in place
- Millipore filters are in place (quantity 3)
- Remove prefilters covering exhaust and inlet air HEPA filter housings. Visually inspect housing to ensure HEPA filters are in place. Replace prefilters.
- Oven door is open & all six trays are on the appropriate shelves
- RTP Alpha door is secured "closed"

**Presentation Content**

**Key Point(s):**

Slide : Place a list of key point here:

- Item 1
- Item 2
- Item 3

**Presentation Notes**  
Step 2.

Instructor presentation notes go here ...

Load the following items:

- Scoops and spatulas
- Sample bottles with associated sample bag, labels, swabs.



Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 9 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Operations - Pre-Run Procedure					

- A container of decontamination or cleaning solution.
- Any other needed equipment (this equipment should be stored in a clean ziplock bag or other closed container)

### Step 3.

Set up the filter with the required basket & filter media into tank ring.



Filter with Top open and filter media installed

### Instructor Notes:

Set up the filter with the required basket & filter media into tank ring. (Note: replace the vessel O-ring when a new process step is started)

### Presentation Notes

Instructor presentation notes go here ...

### Step 4.

Close the filter lid & lock the swing bolts in place. Make connections to the following items in the chamber:

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 10 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Operations - Pre-Run Procedure					



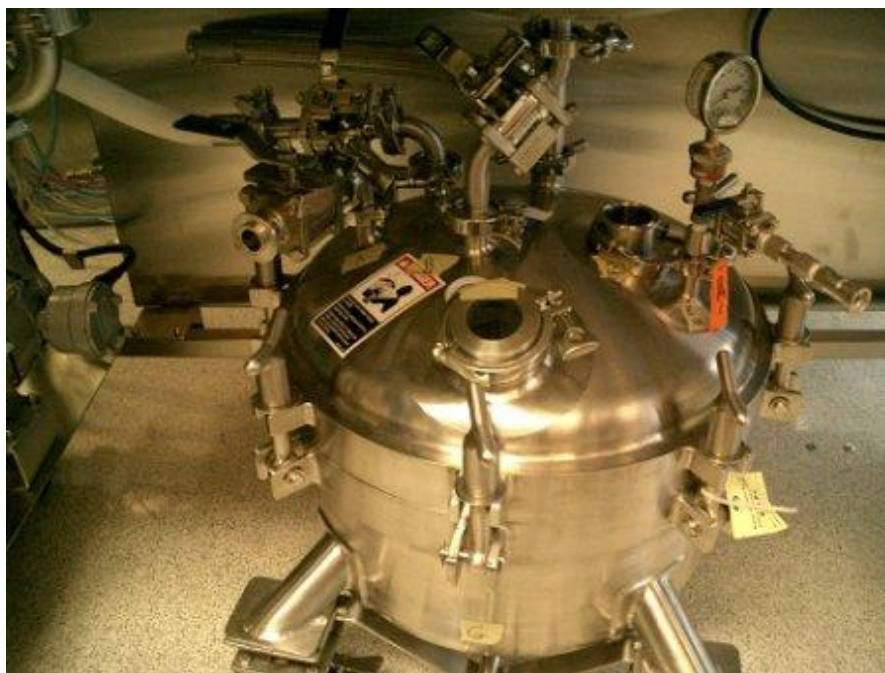
Filter with Top closed (note - not bolted shut)

- From the ceiling nitrogen to the filter
- From the ceiling slurry to the filter
- From the right side CIP solution/filter wash solution to the spray ball connection on the top of the filter.
- From the dryer vacuum connection to a vacuum source which should include a solvent trap if using the onboard vacuum pump.
- From the oven drain to the Mother Liquor Tank.
- From a pressure can with cleaning/decon solution to the spray ball/spray wand (with manual ball valve) connection.
- From the bottom of filter to the mother liquor tank.
- From the bottom of the mother liquor tank to an appropriate holding container for mother liquor. An appropriate waste container should also be available. These containers should be vented to a ventilated area.
- From a nitrogen source to the top of the mother liquor tank.
- From a vacuum source to the top of mother liquor tank.
- Cap the remaining spare ports.

#### Step 5.

Make connections to the following items outside the chamber :

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 11 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Operations - Pre-Run Procedure					



#### Mother Liquor Tank

- From the dryer vacuum connection to a vacuum source which should include a solvent trap if using the onboard vacuum pump.
- From the oven drain to the Mother Liquor Tank.
- From a pressure can with cleaning/decon solution to the spray ball/spray wand (with manual ball valve) connection.
- From the bottom of filter to the mother liquor tank.
- From the bottom of the mother liquor tank to an appropriate holding container for mother liquor. An appropriate waste container should also be available. These containers should be vented to a ventilated area.
- From a nitrogen source to the top of the mother liquor tank.
- From a vacuum source to the top of mother liquor tank.
- Cap the remaining spare ports.

#### Step 6.

Run a vacuum test on the dryer and filter

The test criteria is to evacuate to less than 330 mba, equilibrate for 5 minutes, note the pressure, measure the pressure rise after 15 minutes. If the pressure rise is less than 65 mba the test passes. If it is greater than 65 mba seal any leaks and retest. (note: the filter should be closed and the dryer door to be in an open state before entering next phase) Once both tests >>pass proceed to the next step.

#### Step 7.

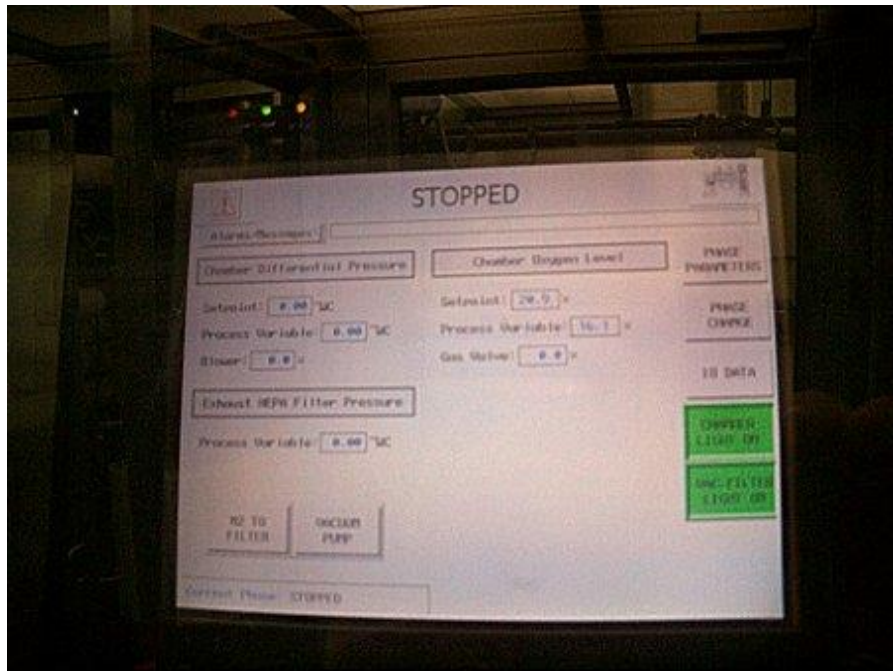
Close the front window and tighten the bolts.

Work Instructions					
Div.No. Error! No document variable supplied.	Dept.No. Error! No document variable supplied.	Rev. No. Error! No document variable supplied.	Effective Date: Error! No document variable supplied.	Replaces Error! No document variable supplied.	Page 12 of 12
<b>Operation and Cleaning of Isolator Contained Tray Dryer/Filters</b>					Originator Originator
Operations - Pre-Run Procedure					

Close the front window and tighten the bolts.

**Step 8.**

Start the system and run a "pressure decay" test from the isolator HMI screen.



**HMI Screen**

Start the system and run a "pressure decay" test from the isolator HMI screen. Once the test passes proceed with the next step. If the power has been off prior to starting the system it can take up to 2 hours for the oxygen sensor to become operational. The system will display an O2 sensor not ready alarm until the sensor is ready.