

QUALITY ASSURANCEDEPARTMENT

S.No.	Item/ Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/ Mechanism	Current Control	Reference document	S	O	D	Priority]	Pos Eval	luat	ion
		(Failure Mode)		of Failure		No.				Num ber (SxOxD)	4	S	O	D	RPN SxOx D
1.	dispensing booth filters to be revised from every change	RLAF Failure	Pressure differential will get disturbed	Leading to increase in Non viable count	Pressure differential is monitored while giving line clearance before each Dispensing.	SOP no.	3	3	3	27	Medium Risk category	3	1	4	12
		HEPA filters integrity	Filters may got chocked	Due to dust collection	Differential pressure is measured/recorded to monitor the filter integrity as per sop	SOP no.	4	2	3	24	Low Risk category	4	1	3	12
		Environmental monitoring.	 Non Viable particle count will increase. Viable particle count will increase 	This leads to cross contamination	➤ Type-A cleaning procedure. •Clean the Area using under RLAF will be cleaned with vacuum Cleaner or clean cloth and the same area will be sanitized with 70% IPA solution. ➤ Type-B cleaning procedure. •After completion of Sampling or Dispensing, Air Blower will be switched "OFF" after 05 minutes from completion of sampling or dispensing activity and Washing the area. •Sampling / Dispensing	SOP no.	4	3	3	36	Medium Risk category	3	2	3	18



QUALITY ASSURANCEDEPARTMENT

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	0	D	Risk Priority Num ber (SxOxD)	(if any)]	Pos Eval O	uat D	tion
					Area under RLAF will be cleaned with Vacuum Cleaner or Lint Free Cloth then Dry & wet mopping of the surfaces and the same area will be	SOP no.									
					sanitized with 70% IPA solution. Cleaning of RLAF. Clean all surface with clean lint free cloth. Use vacuum cleaner. RLAF Unit shall be mopped with 70% IPA Weighing balance	SOP no.									
					cleaning. Clean the pan or platform and exposed parts of the Balance by moping with clean cloth Dispensing tool										
					cleaning. Rinse the Sampling and dispensing tools with hot purified water. Start cleaning the parts with hot purified water after then rinse with hot purified water purified water.	SOP no.									



QUALITY ASSURANCEDEPARTMENT

S.No.	Item/ Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/ Mechanism	Current Control	Reference document	S	0	D	Priority	Recommended Actions]	Pos Eval	uat	ion
		(Failure Mode)		of Failure		No.				Num ber (SxOxD)	(if any)	5	O		RPN SxOx D
		Air flow pattern change	Pre filter may get chocked	If filter not cleaned properly, after every	 Wipe the Sampling and dispensing tools with dry lint free cloth and check the Sampling and dispensing tools visually clean for any adhesive particles and kept in double polythene bag with cleaned status label. Differential pressure verification. After each dispensing activity, pressure differential is monitored 	SOP no.	3	2	3	18	Low Risk category	3	1	4	12
				dispensing activity, filter may get chocked	& filter to be cleaned as per given procedure. Differential pressure in placed to monitor the pressure load checked before every line Clearance										
2.	Return riser cleaning the filter on weekly	Filters may get chocked	Area may get contaminated.	Dispensed material may be contaminated.	Type-A cleaning procedure.Clean the Area using	SOP no.	4	3	3	36	Medium Risk category	3	2	3	18



QUALITY ASSURANCEDEPARTMENT

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	0	D	Risk Priority Num ber (SxOxD)	(if any)]	Post Eval O	uati D	
	limit	Air flow pattern may not get as per requirement.	Area may get contaminated & Return riser filter may get chocked		under RLAF will be cleaned with vacuum Cleaner or clean cloth and the same area will be sanitized with 70% IPA solution. Type-B cleaning procedure. After completion of Sampling or Dispensing, Air Blower will be switched "OFF" after 05 minutes from completion of sampling or dispensing activity and Washing the area. Sampling / Dispensing Area under RLAF will be cleaned with Vacuum Cleaner or Lint Free Cloth then Dry & wet mopping of the surfaces and the same area will be sanitized with 70% IPA solution. As per defined procedure of cleaning Weighing balance & Dispensing tool cleaned	SOP no.									



QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR RLAF CLEANING PROCEDURE

S.No.	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	Risk Priority Num ber (SxOxD)	(if any)]	Post Evalu	uati D	
			& and kept in double polythene bag with cleaned status label.	SOP no.								

Remarks (if any):- Cleaning of dispensing booth filters leads to medium risk, which can be lower down after regular monitoring of pressure differential and verification of RLAF cleaning procedure.

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	Regular monitoring of pressure differential to be done for 09 days or whenever D.P. limit exceeds its limit before increasing cleaning frequency.		
2.	RLAF cleaning procedure to be verified with approved protocol.		
3.	SOP Cleaning of Reverse Laminar Air Flow Filters and Grills to be revised.		

CAPA (Required / Not Required): If required, mention CAPA No.:

Quality Risk Management Tear	n		Reviewed By	Approved By
Name	Department	Sign & Date	Head Operations	Head QA
			(Sign & Date)	(Sign & Date)

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR RLAF CLEANING PROCEDURE

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation: Procedure

Verification of Recommended Action:

Remarks (if any): Recommendation of regular monitoring of pressure differential to be done DP limit exceeds its limit before increasing cleaning frequency and RLAF cleaning procedure to be verified with approved protocol will be completed till the end of, Further SOP "Cleaning of RLAF and Grills" has been revised.

Verified By Officer/Executive QA (Sign & Date) Approved By Head QA (Sign & Date)