STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification Planner	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Qualification Planner.

2.0 SCOPE:

This SOP is applicable for Qualification Planner of all the Equipment/Area handled and Qualified at……..

3.0 RESPONSIBILITY:

QA (Officer/Executive)

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

PRECAUTION:

Do not use non Qualified Equipment/Area.

6.1 EQUIPMENTS/AREA - QUALIFICATION:

6.1.1 Manufacturing equipment shall be qualified for intended use and shall be assigned with a unique ID. No. as its identity. QA Department is responsible for assigning the ID Number independently for all equipment and utility.

6.1.2 Qualification team i.e. Quality Assurance, Production, Quality Control and Engineering Department along with vendor (manufacturer) (where applicable) shall qualify the equipment installed in the Production area & warehouse and identify the Equipment **"Equipment Qualification Status Label" as Annexure-I**.

6.1.3 Qualification protocol contains the procedures, Frequency and acceptance criteria and precautions and to be followed the same.

6.1.4 Qualification of equipment/area, done at defined frequency. However, when equipment is in operation and/or for any other reasons Qualification could not be done at due

Period, it must be qualified under the tolerance period as mention accordingly:

Qualification	Set Frequency	Tolerance
Production Equipment	Half year ,1 & 2 Years	± One Month
Area Qualification/HVAC	Half Yearly,1 & 2 Years	± One Month
Utility	Yearly	± One Month

Due to any reason, if Qualification due date exceeds the delay in Qualification shall be approved by Head QA.

6.1.5 Any Qualification done by external person / agency shall be recorded and maintained with its relevant record. The Officer / Executive in qualification team shall ensures the equipment is Qualified before putting into operation.

6.1.6 A Master Qualification Planner shall be maintained for all the equipment's /Area as shown in **Annexure-II** for Periodic Qualification of Calendar year.

6.1.7 The first column of the Annexure-II i.e. "Name of Area" shall have only name of the main core area specially in case of AHU's.

6.1.8 The first Planner of the year shall have a revision no. as 00 and whenever there will be any changes in the planner due to addition/deletion or any reason, the revision no. shall be changed accordingly to next revision no. during the same year.

6.1.9 For routine Qualification, either Annual Contract or Annual Arrangement shall be made with Equipment manufacturer/Authorized Agent. Frequency of Qualification shall be followed as per the contract. A Qualification Protocol & Report shall be maintained by the Quality Assurance Department.

6.1.10 For routine servicing and maintenance, either Annual service contract or service arrangement shall be made with Equipment manufacturer/authorized Service agent. Frequency of servicing shall be followed as per the contract. A service report shall be maintained by the respective Department.

7.0 ABBREVIATIONS:

SOP Standard Operating process

QA Quality Assurance

ID Identification

AHU Air Handling Unit

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Equipment Qualification Status	
Annexure-II	Master Qualification Planner Execution Record	
Annexure-III	Under Requalification status	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department.
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.

10.0 REFERENCES:

Validation Master Plan

WHO TRS 937

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification Planner	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–I

EQUIPMENT QUALIFICATION STATUS

EQUIPMENT QUALIFICATION STATUS
Equipment Name : ----------
Equipment Location : ----------
Equipment ID No. : ----------
Qualification Done On : ----------
Qualification Due On : ----------
Qualification Done By : ----------

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification Planner	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–II

MASTER QUALIFICATION PLANNER EXECUTION RECORD

Name of Area	Name of Equipment	Equipment ID No.	Qualification Done Date	Re-Qualification Test details with due date	
				Test to be performed	Next Due Date

Prepared By
Officer/Executive-QA
Sign & Date

Checked By
Department Head
Sign & Date

Approved By
Head Quality Assurance
Sign & Date

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Qualification Planner	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–II

UNDER QUALIFICATION STATUS

UNDER QUALIFICATION STATUS
Equipment Name :_____ **Equipment ID No. :**_____ **Requalification Start on :**_____ **Frequency :**_____ **(Sign & Date)**