

STANDARD OPERATION PROCEDURE		
No. : ENGP-218	FAILURE MODE EFFECT ANALYSIS (FMEA) OF AIR HANDLING UNIT (AHU)	Date Of Issue
Version No.:01		Effective Date
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PURPOSE:

To provide a procedure for FMEA of AHU.

SCOPE:

Applicable to AHU.

RESPONSIBILITY:

AHU validation team member.

DEFINITION:Not Applicable

1.1 **HEALTH, SAFETY AND ENVIRONMENT :** Not Applicable.

2.1 **PROCEDURE:**

- 2.1 Start the AHU of area under study.
- 2.2 keep the AHU in running condition for at least 30 minutes after switching "ON" the AHU (Recovery Period).
- 2.3 Switch "OFF" the AHU and record the time.
- 2.4 Start taking particle count at all predetermined location.
- 2.5 Record the time at which area loses the desired particle count at either of the locations.
- 2.6 Conclude the time within which area will losses desired particle count at either of the locations by following formula.

Time period required to lose particle count= (Time at area loses desired Particle count is failed at either of the location.) – (Time at which AHU is switched OFF)

PREPARED BY Department Head <i>Date:</i>	APPROVED BY Quality Assurance <i>Date:</i>	AUTHORISED BY Unit Head <i>Date:</i>
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- २,१ Switch “ON” the AHU and record the time.
- २,२ Continue the particle counting at all locations till the desired cleanliness class of area is achieved at all locations.
- २,३ Record the time at which desired particle count i.e. Cleanliness of area is achieved at all locations.
- २,४ Conclude the time within which area will regain particle count at all locations after restarting the AHU by following formula.

Room condition regain period = (Time at which the desired particle count is achieved at all locations) – (Time at which AHU is restarted)

३,१ **FREQUENCY:** Once in a two year.

४,१ **ABBREVIATIONS:**

AHU : AIR HANDLING UNIT

ISO : INTERNATIONAL ORGANISATION FOR STANDARDS

RH : RELATIVE HUMIDITY

FMEA : FAILURE MODE EFFECT ANALYSIS

i.e. : THAT IS

५,१ **REFERENCES:**

ISO-14644-1-CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS.

६,१ **ANNEXTURE:** Not Applicable

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