

HVAC Systems

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HVAC -

A properly designed HVAC system can:

Heat

Cool

Humidify

Dehumidify

Supply clean
air

Dilute
airborne
contaminants

Capture
airborne
particles

Create room
differential
pressures

HVAC cannot clean up contaminated surfaces or protect from poor operator practices

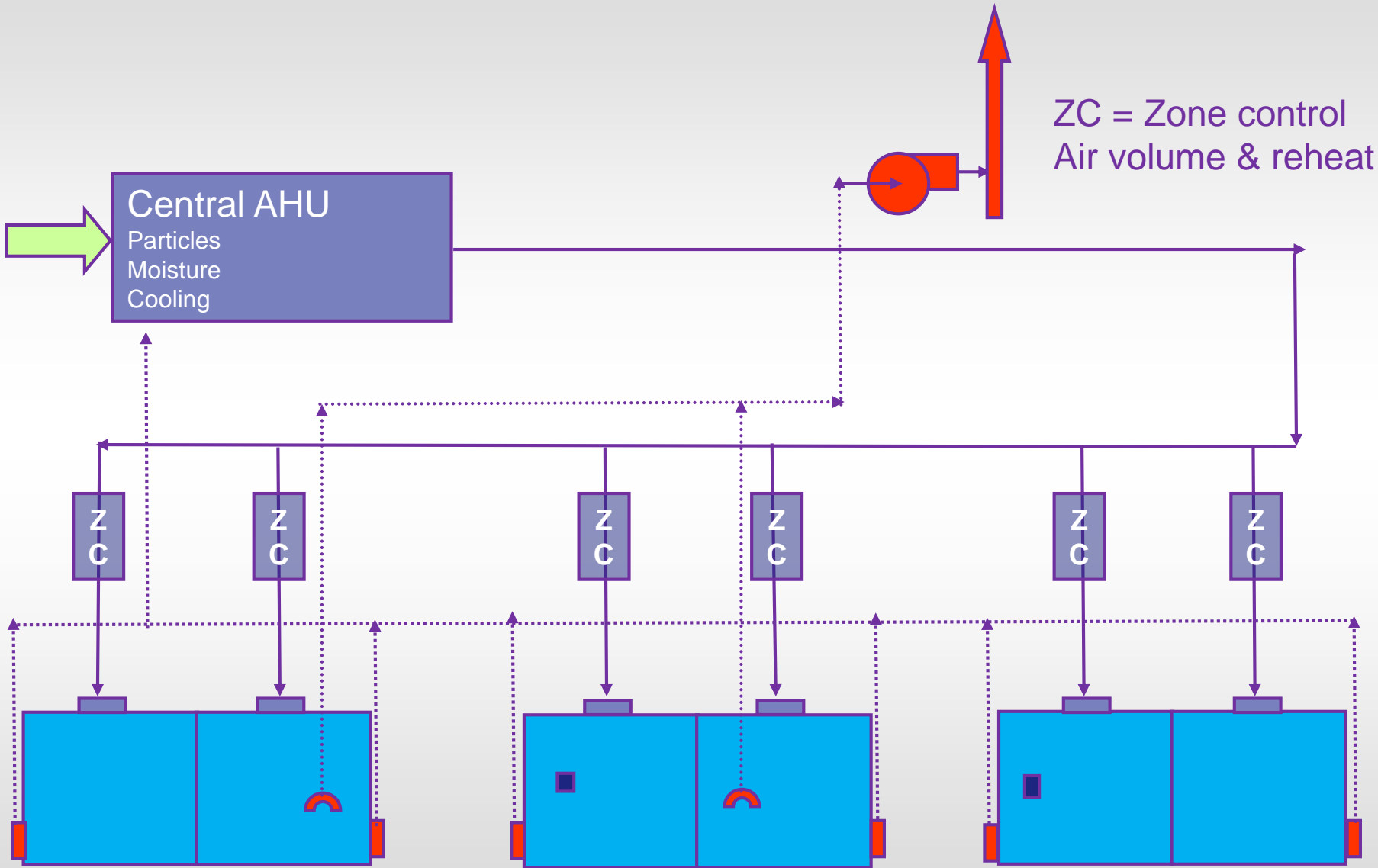


Drains and Traps

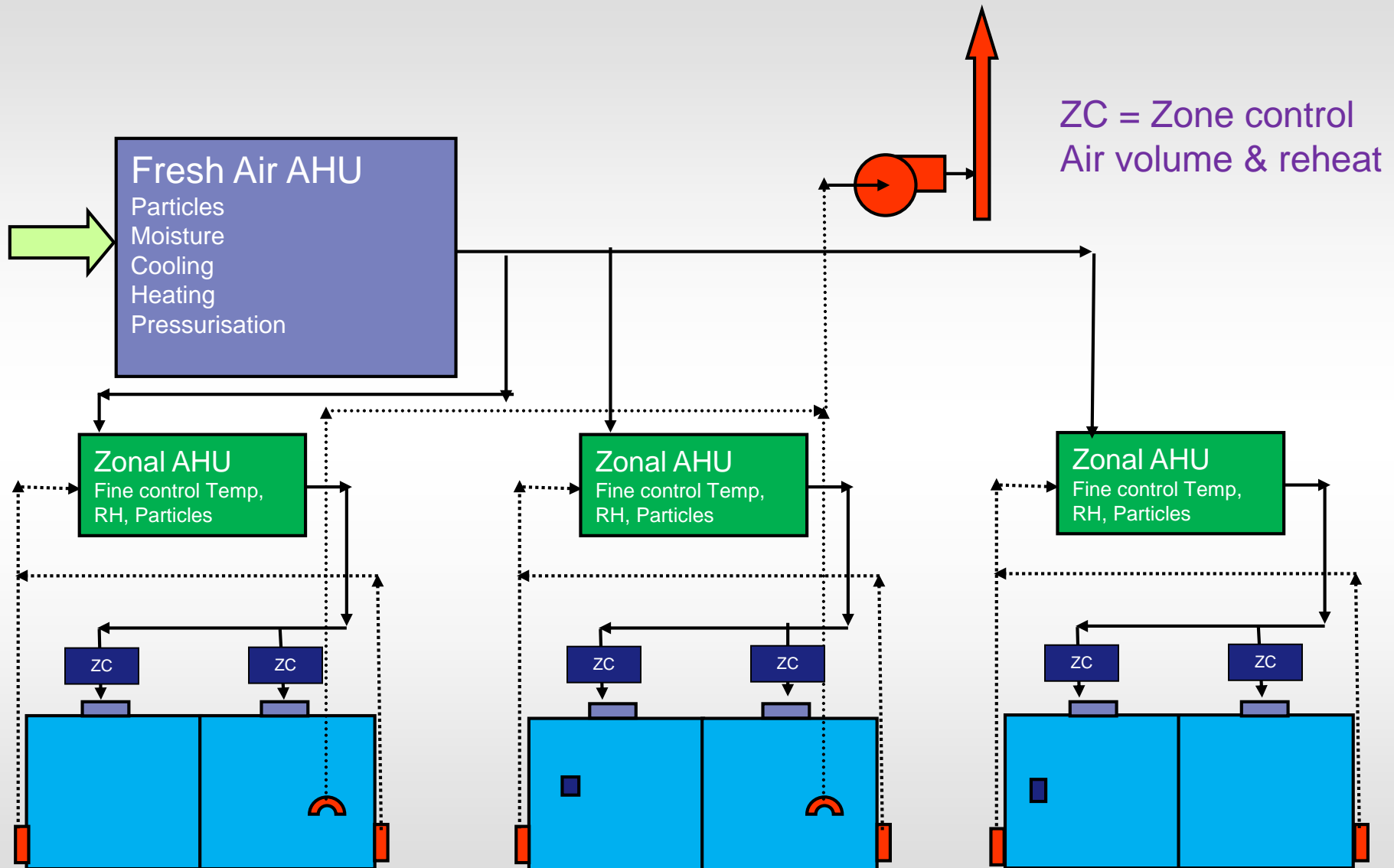
- Collect condensate from cooling coils
- Provide traps from drain pans
- Ensure traps are full at all times



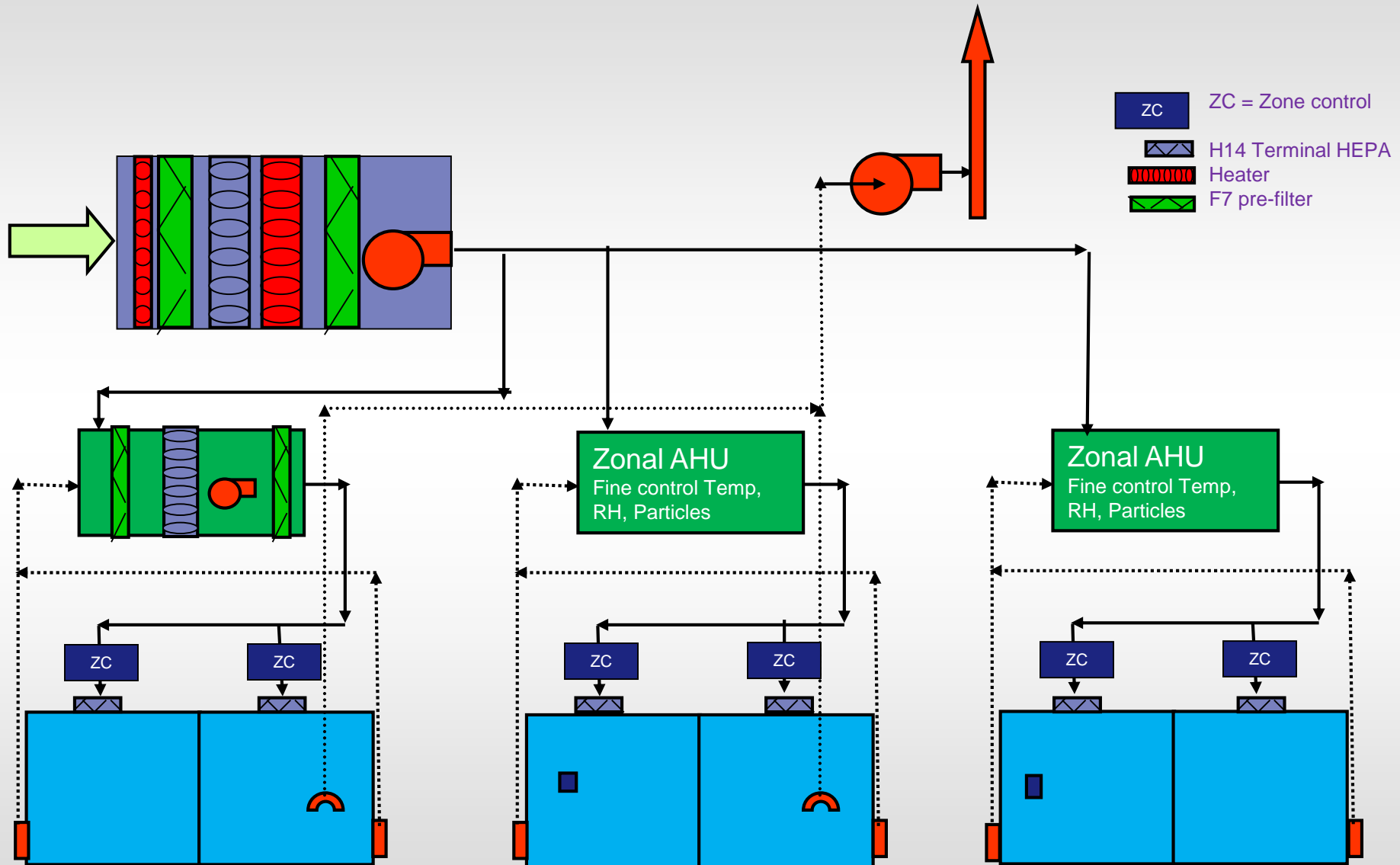
Systems Configuration – Single Plant



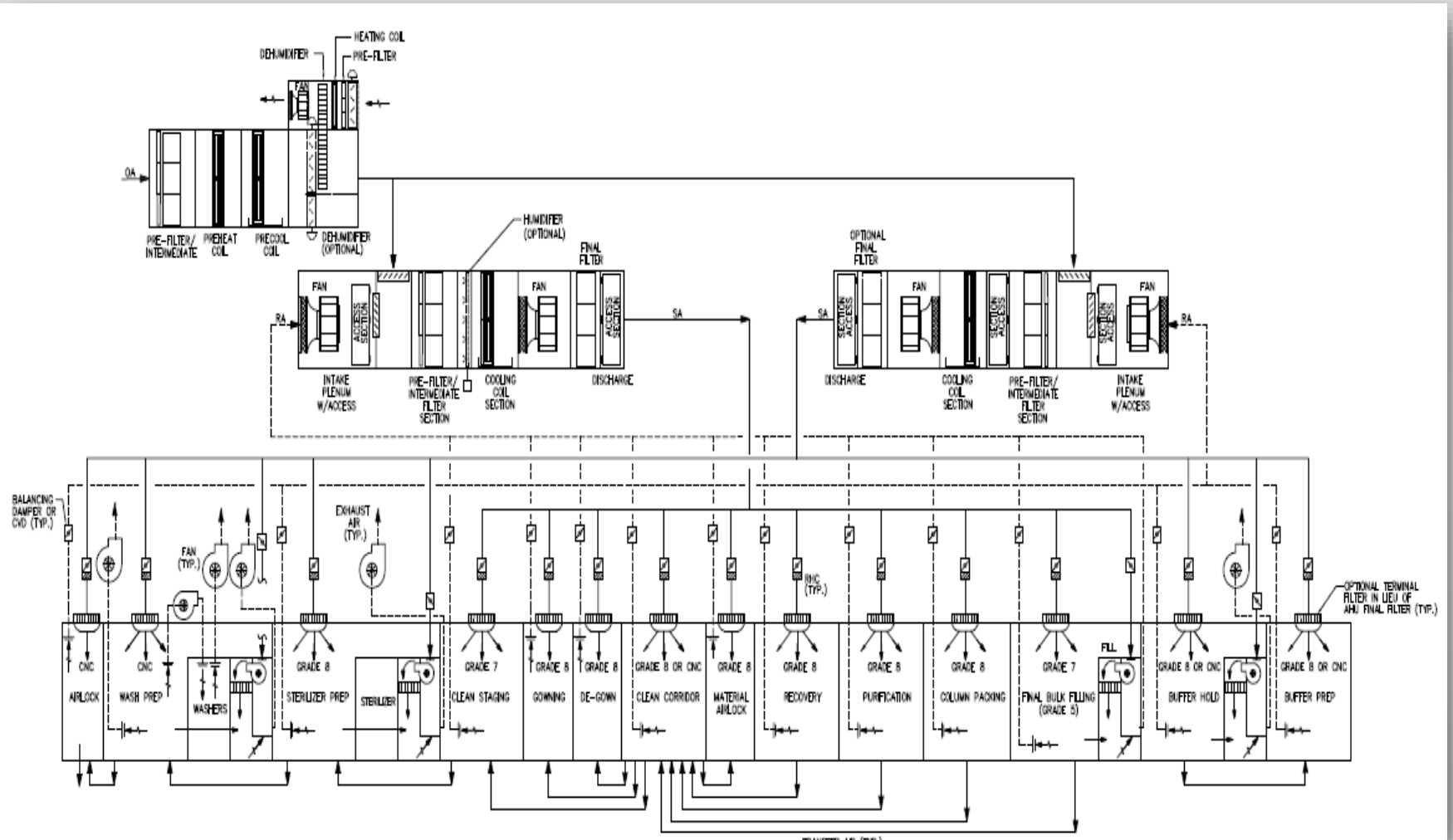
Systems Configuration – Multiple Plant



System Details – Multiple Plant



Sterile/Biologics Systems



How Many Air Changes are Enough?

In addition to meeting these requirements the following need to be considered when **designing facility air supply**:

Heat Gain

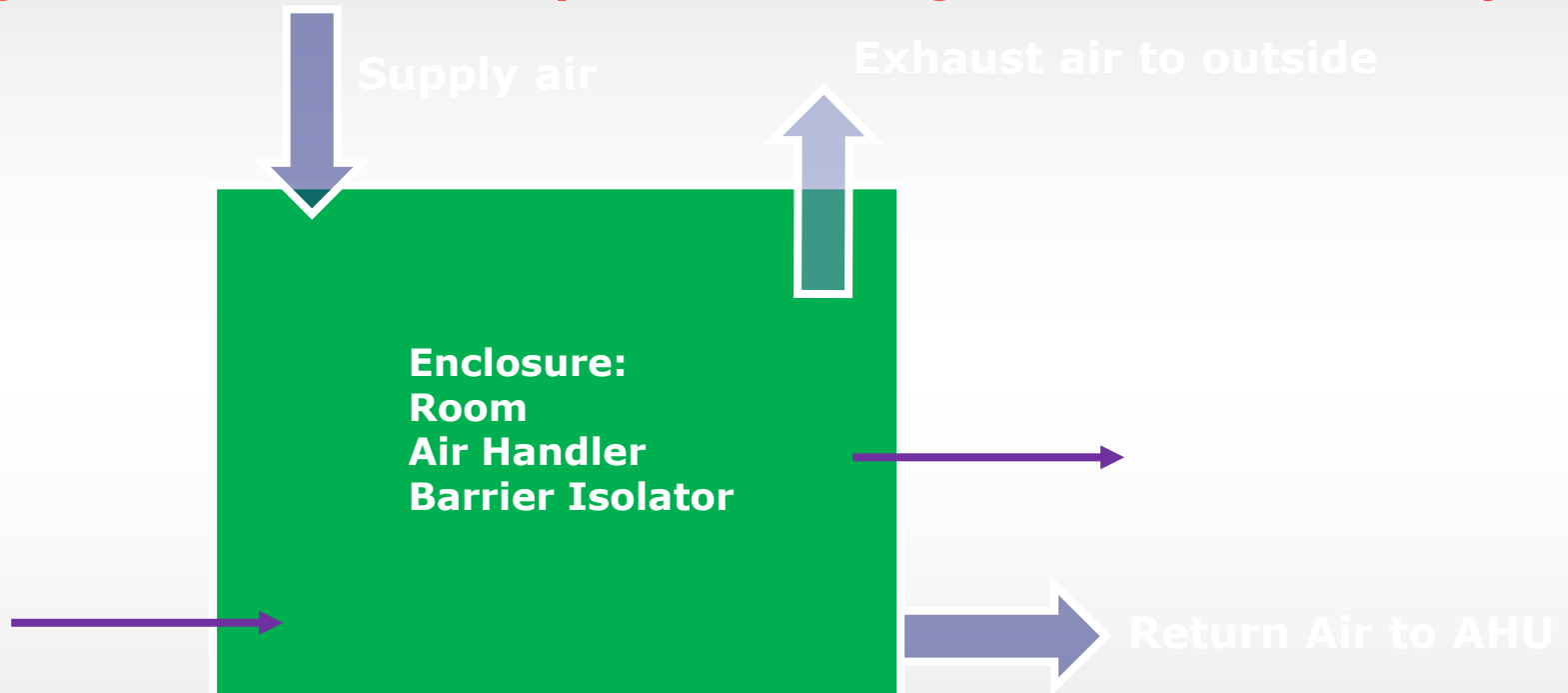
Exfiltration loss (pressurisation)

Particulate Gain

Recovery Time

Air Balance

What goes in must come out (we deal with rigid enclosures in HVAC)



AIR IN = AIR OUT

Supply + Infiltration = Return + Exhaust + Exfiltration

Heat Gain

This is all of the heat energy that is present in the room and includes:

Body heat from
personnel

Heat from lighting

Heat from equipment

Heat from air that is
recirculated without
passing through a
cooling coil (e.g.,
UDAF Hoods)

Assumes an Interior Room

Exfiltration Loss

This is the air that...

Escapes through cracks, passes under doors

Passes through mouse-holes

Passes into equipment

Estimation of Leakage

- Designer must estimate the leakage rate
- Designer must allow for any unknown leakage rates
- Doors should be the main leakage path
- Leakage rate through small gaps can be determined from:
 - $Q = 0.827 \times A \times (DP)^{0.5}$

Where

- Q = leakage rate m³/sec
- A = leakage area m²
- DP = differential pressure between spaces Pa

Recovery Time

The "recovery" time for a cleanroom is the time required for the particle count level to return to its "at rest" condition after production ceases and personnel leave the room. The "recovery" will follow an exponential curve, so it may take a long time to achieve its "at rest" condition.

Annex 1 Requirement

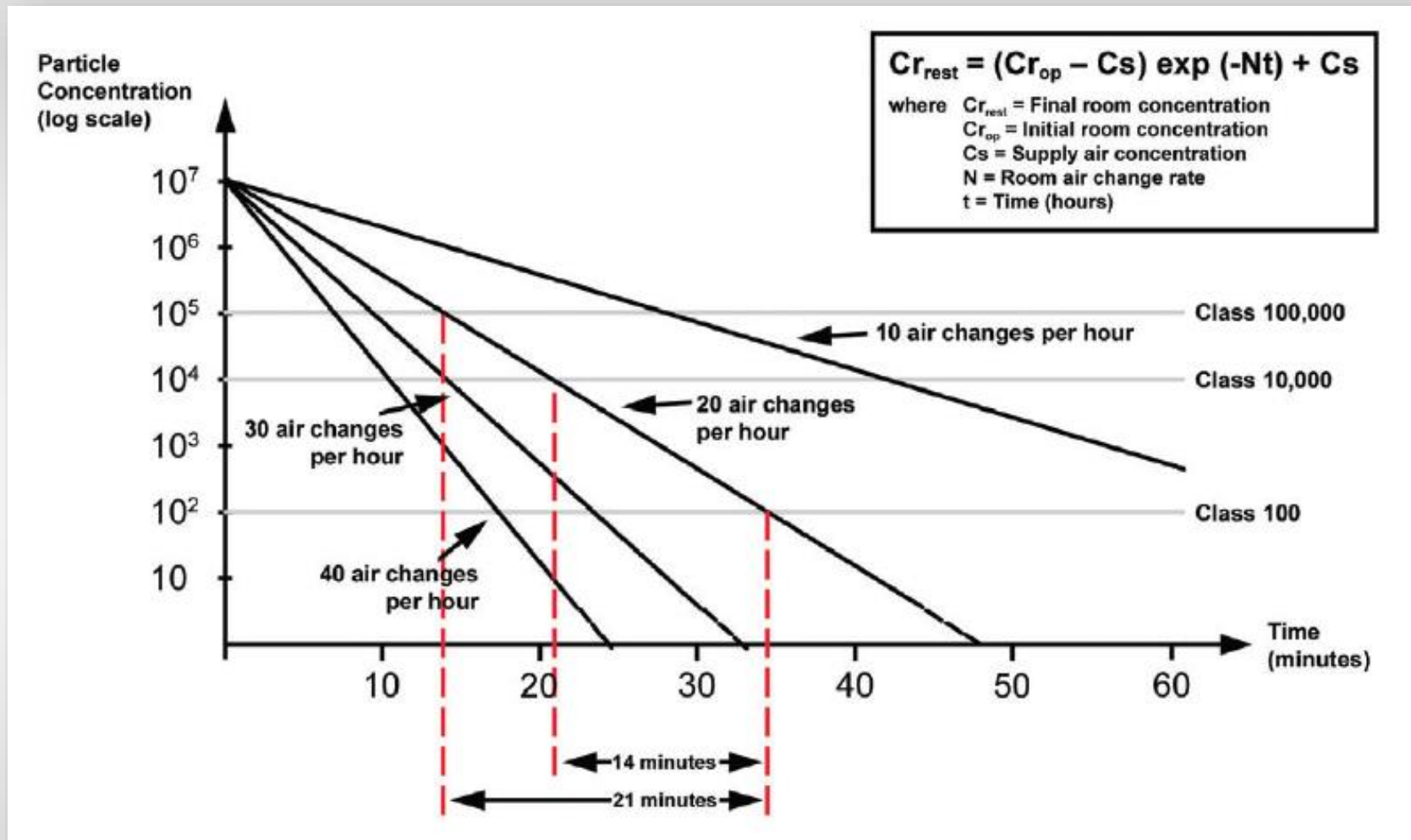
- The particulate conditions given... for the "at rest" state should be achieved after a short "clean up" period of 15-20 minutes (guidance value) in an unmanned state, after completion of operations.

Annex 1 Airborne Particle Classification

Recovery time

Grade	Maximum permitted number of particles/m ³ equal to or above:				
	In Operation		N/A for UDF After 15 – 20 minute cleanup →	At Rest	
	0.5 µm	5 µm		0.5 µm	5 µm
A	3520	20		3520	20
B	352,000	2,900		3520	29
C	3,520,000	29,000		352,000	2900
D	Not Defined	Not Defined		3,520,000	29,000

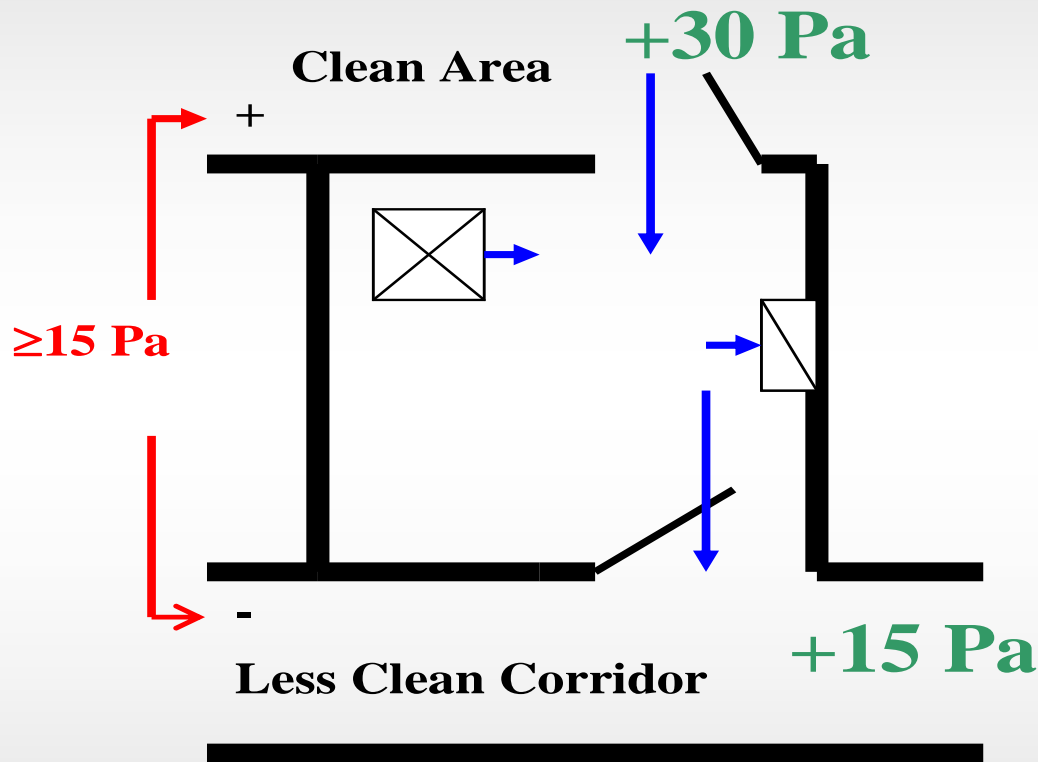
Recovery Time



ISPE Sterile Baseline® Guide, Page 146, Figure A3.5

Classic Cascading Pressure Airlock

(as anticipated in our GMPs)



Conversion: $0.05 \text{ in H}_2\text{O} = 12.5 \text{ Pascals}$

Typical HVAC cGMP Problems

Control of room pressure fails or drifts

Temp/RH excursions during extreme external weather conditions

Unscheduled failures / downtime

Controls: Building Automation System

Field Devices – calibration drift

Inadequate design capacities current / future

Inappropriate design conditions (too tight & too loose)

HVAC – Ductwork Key Design Issues

Leakage rates

Inspection ports for

- Filters
- Devices
- Cleanouts

Insulation/rust inhibition

Delivered clean to the jobsite

NOTE: Ductwork is not specifically mentioned in cGMPs, but clearly the entire delivery system must be considered as “equipment” to be controlled.

Thank you for your time.
Questions?



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