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MODELING AND ASSESSMENT OF INDOOR AIR QUALITY IN A SINGLE-ZONE CLEAN AREA OF A COLD KIT FACILITY FOR NUCLEAR MEDICINE PURPOSES

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Indoor air quality (IAQ) is a standard term referring to the cleanliness of air with respect to airborne contaminants or particles of any size. The goal of a general ventilation system in any critical area is to control these airborne pollutants below presetting and standard concentrations, while keeping as well comfortable environment. The quality of the air in any dedicated clean area for medical purposes is essential requirement for hygienic purposes in many applications. One of these applications is Cold Kit Production Facility (CKPF). Radiopharmaceutical product is produced in this sterilized clean area for humans. Ministry of Health and Populations the regulatory authority that establishes regulations of this type of facilities in addition to the local nuclear regulators inside the country are responsible for licensing it according to many rigorous procedures, measures, restrictions and precautions. One of the important criteria affecting product quality and its hygienic integrity is sterility of the surrounding environment. Air cleanliness and quality in the production area are the main focus of this study and the web-based Model for the Fate and Transport of Indoor Microbiological Aerosols is used to predict indoor air contaminants based on several key parameters such as filter efficiencies and classes, supply and re-circulated air flow rate, exhausted air, tightness of the area envelope, number of air changes per hour and workers activities inside the area. Internal air cleaner represented in using high efficiency filters is also studied to assess its effect on air quality and individual exposure during the considered working time. The study considers a pollutant size of 0.5 µm, while its concentration is predicted in rest and operation condition. The quantity of pollutants is measured with a specialized instrument at steady state to validate the model predictions.

Keywords: ventilation, clean area, airborne pollutant, air change, concentration

1. Introduction

Cindy Bekker et al. [1] reported a study of the dispersion of manufactured nanoparticles through the air, in space and time, during the use of two traditional available nano-spray products and comparable products. It is shown that personal exposure to manufactured nano-objects occurred not only in the near location, but also at a greater distance than the immediate proximity of the source and at a period after emission occurred. The air movement and aerosol particle concentration and deposition in displacement and mixing ventilation rooms are studied numerically by Zhao Bin [2]. He showed that deposition of pollutants and their concentration are mainly affected by the condition of ventilation system. For similar pollutant characteristics, a room ventilated by displacement has a lower rate of deposition and a greater escaped pollutant mass than the mixing one, while the average concentration of the displacement case is higher than the mixing case. It is also found that particles of different sizes (1, 2.5, and 5 µm) have different movements in the two studied cases of ventilated rooms.

Mohamed Abuhegazy et al. [3] investigated, using computational fluid-particle dynamics simulations the transport of aerosol and its deposition process on surfaces in a realistic classroom environment. The influences of aerosol source location, particle size, and windows were demonstrated that aerosol transport in air follows some stochasticity. The trajectory of a dispersed toxic particle and the probability of approaching others in the same ward were calculated by Ji-Xiang Wang [4]. Two parameters are presented and evaluated, total maximum time and overall pollutant concentration to reflect the mobility of pollutant and its probability to bring about cross-infection respectively are developed to evaluate the proposed ten air distributions. A relatively optimized air distribution is proposed with the lowest maximum time, and particle concentration is distinguished through a three-stage analysis. A bottom-in and top-out air distribution was recommended to minimize cross-infections.

Ralph Stuart et al. [5] studied the concentration decay rates of carbon dioxide at different locations in the room after increasing the CO_2 level across the room above 10,000 ppm. It is concluded that the locations of

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air-supply and air-removal diffusers in the room; the furniture laboratory layout, equipment, the location of windows and doors in the lab and their relative leakiness to adjoining areas influence the distribution of pollutant concentrations. H. Qian and Y. Li [6] studied in detail the numerical and experimental distribution of the particles exhaled by humans and gaseous pollutants in a full-scale experimental isolation room with downward supply and three various exhaust designs. It is concluded that for fine particles and gaseous pollutants, the system with only ceiling level exhaust in the isolation room can remove the pollutants and fine particles more efficiently than the system with only floor level exhausts and the system with exhausts at both levels. For large particles, depositions played a greater role in removal.

Whyte [7] studied the redispersion factor of microbe-carrying particles. It varied according to conditions in the room, including air supply rates, levels of personnel tasks and activities, and the effect of gravitational deposition on microbe-carrying particles. Rajeev Kumar [8] presented work contains the details of air diffusion and comfort issues of an isolation room of a hospital in two cases of unidirectional ventilation system of the isolation room i.e. for immuno-suppressed patients and infectious patients including the motion and average residence time of a contaminant that could possibly accompany the supply air and the bacteria that can be released from an infectious patient's mouth by means of breathing, coughing or sneezing.

Huai-Wen [9] studied improvements in ventilation and air quality of densely occupied multipurpose rooms in elderly care centers by investigating the impact of different ventilation types on ventilation performance and air quality, analyzing as well the influence of ventilation on CO_2 concentration; and discussing appropriate ventilation design comprehensively considering air change efficiency, mean age of air and contaminant removal effectiveness.

Arup Bhattacharya [10] presented the results of many experiments to attribute the influence of pressure difference, door opening and traffic flow on cross contamination and the quality of air inside the cleanroom. The experiments were conducted in a real cleanroom where an oil-based substance was aerosolized in neighboring rooms, and its pathway inside the cleanroom was studied. It is concluded that the higher pressure differentials and door operation were more effective in preventing aerosols from entering the cleanroom.

Bin Zhao [11] studied particle diffusion with sedimentation in a clean room with different modes of ventilation and different particle sizes of 0.3–20 μm in two different clean rooms with two different air exchange rates and particle source locations. It was shown that ventilation mode, particle source location and air exchange rate can affect particle distribution in a clean room.

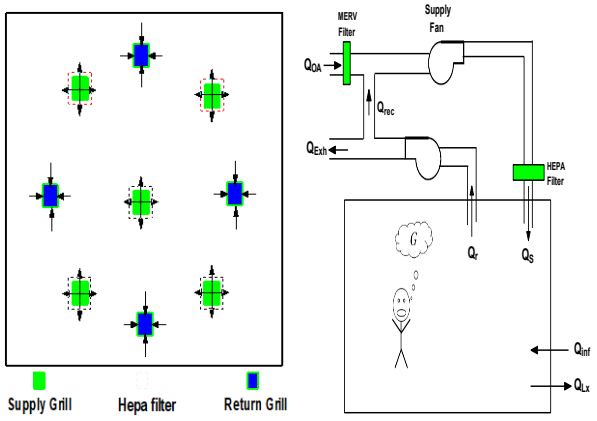
Haifeng Bao [12] simulated the ophthalmic negative-pressure operation room using the Eulerian–Lagrangian method to investigate the airflow field and bio aerosol distribution during surgery with assessment of internal air cleaner at different airflow parameters. It is shown that increasing the airflow temperature and decreasing the relative humidity is a reasonable option. It is concluded as well that there were really useful insights for developing rational mitigation strategies and reducing the cross-infection risk in ophthalmic hospitals.

Our ventilation system and clean-area design for the cold kit facility are still under construction. This manuscript examines design parameters to predict contaminant concentrations inside class B area based on these design parameters such as air changes per hour, supply air, filter classifications, pollutant sources, recirculation rate, infiltration, and resuspension factor that follow and comply with international standards like WHO and local regulation represented in Egyptian Drug Authority (EDA). Keeping particle concentrations below the limit will enhance sterilization quality and product sterility. The goal of this manuscript is to verify that these design parameters yield results that comply with international standards with studying as well other parameters to predict the differences.

2. Mathematical model

The equation describing the model in *Figure 1* applies to a single-zone area of uniform pollutant concentrations and was presented by W. Stuart Dols [13],[14]. The model uses an air handling unit that provides required air to and re-circulated air from this zone. Five well-distributed supply openings are provided to supply the area with air to satisfy good air distribution, while four openings are assigned for recirculation. HEPA filters are distributed regularly on the ceiling before each supply opening and both supply-air streams (fresh and recirculated) are mixed together to pass through HEPA filters and supply openings, while MERV filters are positioned in the SAHS entrance to clean fresh air only before its mixing with circulated air in mixing plenum on air handling unit as shown in *Figure 1*.

The supply and recirculated airflow rates and the outside-air fraction are entered by the user, and the



(a) (b)

Figure 1: (a) Single zone model representation, (b) supply and return ceiling openings representation and HEPA

simulation model estimates the area air balance results, including the outside-air intake and the infiltration to zone. If the provided and re-circulated airflows are not balanced, the area will therefore be either negatively or positively pressurized, thus determining the value in *Equation 1*. The single-zone mass-balance equations for the zone space and interior surface areas are given in *Equations 1 and 2*. *Equation 1* depicts the time rate of change in pollutant mass within the zone air is equal to the rate at which pollutants are added to the zone air via infiltration, from the supply airflow and through resuspension and removed from the zone air by recirculated airflow and deposition to the assigned surfaces in the room. *Equation 2* illustrates the time rate of change of pollutant mass on the surfaces of the room is equal to the rate at which particles settle and are deposited on the walls or surfaces from the air minus the rate of resuspension to the air. Model calculates all contaminant in mass units. However, it also converts to pollutant number unit based on its density and its size.

$$V\frac{dC_z}{dt} = Q_{inf}.C_{\alpha,oa}(t) + Q_s.C_{\alpha,s}(t) + G(t) + \sum_{i=1}^{N_s} r_i.A_{ri}.L_{\alpha,si}(t) - (Q_r + Q_{lx} + \eta_{ac}Q_{ac}).C_{\alpha,z}(t) - \sum_{i=0}^{N_s} v_{di}.A_{si}.C_{\alpha,z}(t) \quad (1),$$

$$\frac{dL_{zsi}}{dt} = v_{di}.C_{\alpha,z}(t) \quad (2),$$

$$R_\alpha(t) = mult.k_d.V_z.\rho_{air}(t).C_\alpha(t).S_\alpha(t) \quad (3),$$

$$S_\alpha(t) = v_d.(ctrl.A_r).L_\alpha(t) \quad (4).$$

2.1. Sources of contaminants

The source of contaminants during study our zone in operation is described as follows:

- Coughing represents an instantaneous addition of pollutant mass to area which is considered a burst source,
- This source emits contaminants based on the following equation:

$$S_\alpha(t) = G_\alpha - R_\alpha C_\alpha(t) \quad (5),$$

- Contaminants from outside air infiltration, which is expressed by:

$$\text{Number of contaminants} = Q_{inf}\left(\frac{ft^3}{hr}\right) x \text{ number of contaminants per cubic meter} \quad (6).$$

The resulting contaminant influx is expressed as a source rate in #/h.

2.2. Single-zone mass balance model

Our single-zone case assumes uniform particle concentrations with a simple air handling system (SAHS) that provides required fresh air to zone and removes return air from the zone. The supply and return airflow rates, Q_s and Q_r, respectively, and the outdoor air fraction of the SAHS are user inputs as variable, and the SAHS model determines the resulting zone air balance, including the system outdoor air intake Q_{oa} and envelope infiltration Q_{inf}. If the supply and recirculated airflow rates are unequal and unbalanced, the area will be either positively or negatively pressurized, thus estimating the value of Q_{inf} in *Equation 1*. The single-area mass balance formulas for the area volume and internal surrounding surfaces are indicated respectively in *Equations 1 and 2*. *Equation 1* depicts the following: transient change in mass of pollutants within the room air is equal to the rate that pollutants are deposited to the area air, so the source of pollutant originates from:

- Outside air by mechanism of infiltration and from the provided airflow of the air handling unit,
- Resuspension on considered surfaces,

And the removed pollutants from the area air is via

- Re-circulated airflow of the air-handling unit deposition to the room surfaces.

Equation 2 depicts the time rate of change of pollutant mass on the surfaces of the area is equal to the rate that pollutant is deposited on the surfaces from the air minus the rate at which they are re-suspended to the air. The model calculates all pollutant in any mass-based units. However, the web based tool is able to convert to pollutant number units (#) based on its size and density.

3. Methodology and considerations

The methodology provides details of the input and output parameters of only single-zone model as shown in *Figure 1*. Parameter names reflect those shown in *Equations 1 and 2*. Area inputs are used to define the properties of the area and ventilation components, source of particles, way of removal and the workers exposure time. Setting the factor of penetration (P) is considered. It has an impact if the concentration of outside air is greater than zero and has imbalance between the supplies and re-circulated rate of airflow which leads to infiltration. Inlet airflow (Q_s) and re-circulated airflow (Q_r) can be controlled and varied in air handling unit. Outside air percentage is adjusted as the fraction from outside air (Q_{oa}/Q_s) of air handling unit. This value should be less than 100% because room air to be re-circulated through the handling unit. If re-circulated amount of air is greater than zero, then the air in area zone can be cleaned or not prior to being mixed into the provided air. Outdoor airflow rate is estimated from the preceding parameters for reference. It is the quantity of outside air assigned into the area via the unit of air handling (Q_{oa}). Airflow exhaust rate (Q_{exh}) is estimated from the preceding parameters. It is the quantity of return air expelled to outside via the air handling unit:

$$Q_{exh} = Q_r - Q_{rec} \quad (7).$$

The air imbalance is estimated from the preceding parameters. It represents the quantity of either air exfiltration or infiltration directly between the area under study and outside air (Q_{inf}):

$$Q_{inf} = Q_s - Q_r \quad (8).$$

If the flow imbalance is negative, it indicates infiltration, in which case the factor of penetration can remove particles from the infiltrating air.

The zone air balance, Q_{bal} indicates whether the zone is positively, negatively or neutrally pressurized:

$$Q_{bal} = Q_S + Q_{inf} - Q_r - Q_{lx} \quad (9).$$

If the value is negative, then the air change rate is increased beyond that attributed to outdoor air intake by the ventilation system and the specified infiltration.

The area air balance shows the imbalance of air flow rate leads to be balanced, pressurized or depressurized area depending on the ventilation rate of airflows. Air filters are selected based on their minimum efficiency reporting values (MERV) to consider within the outside and/or returned air streams of the air handling unit as shown in *Figure 1*.

The *Equation 1* in model description shows concentration variable (C_a) per cubic volume of air. All equations are solved simultaneously by finite difference methods using input data such as, provided air quantity, recirculation air quantity, volume of area, size of pollutants, initial concentration, particle concentration in supply are *Table 1*, number of air changes per hour, infiltration assumption and filter efficiencies.

3.1. Deposition with resuspension

Resuspension is related to the areas of floor, wall, and ceiling (Ar_i), rates of resuspension (r_i) and units for each type of surface from which to consider for pollutant resuspension, i.e., adding the pollutants to air in area by resuspension. The areas of resuspension are not needed to be similar to areas under room geometry, but they may be lesser than or equal to those areas. In this source model, pollutants are removed from the air by depositing on a surface with emitting source via mechanism of resuspension from the walls. The overall deposition wall area remains constant as estimated by the (mult·As) part in the equation above, but the rate of resuspension and space area can be updated by a control value or a schedule.

3.2. Surface loading

Walls, floor, ceiling, and others are the resultant masses or number of pollutants deposited on each of the mentioned surface types divided by their respective surface areas as defined in the section of zone geometry.

$$L = \frac{\text{Mass or number of particles depsited}}{\text{Respective surface area}} \quad (10).$$

3.3. Model consideration

Inputs to model contain properties of pollutants being considered. Biological contaminants are typically assumed to be droplets or smaller droplet nuclei containing microorganisms, e.g., microbes or viruses. The terms contaminants and particles refer to the individual components of the pollutants, of user input to define its size, deactivation, half-life [15] and its density.

Table 1: Summary of outdoor contaminant concentrations off-site

Outdoor contaminants	Daily average contaminants concentration			Peak contaminant concentration	
Measurement no.	1	2	3	Min	Max
PM 0,5 µ.ft^{-3}	1.7E6	1.98E6	2.31E6	1.528E6	1.798E6

In addition, the loss of contaminants through the room envelope is achieved by pollutant penetration coefficient (P). It expresses the ability of pollutants to enter the area envelope.

4. Model validation

Particles were measured using a calibrated device (EPC Ergotouch ET-01) Ergotouch [16] airborne particle counter as shown in *Figure 2*. The device was set to measure particle size 0.5 µm and concentration in British unit in #/ft^3.

The steady-state value was predicted and measured over time considering the area at rest to validate our simulation model. *Figure 3* demonstrates concentration of particles or contaminants in the area. The predicted value of concentration per cubic meter of air inside the area was found to be 1904 #/m^3. Measured values are compared with the predicted values and were within acceptable limits.

The model was also validated against another model by Zhou [17] in *Figure 4*. Particle concentration is positively affected by the number of air changes and concentrations decrease as the number of air changes increases from 40 to 120 in both cases of low and high particle emission rate. The low and high emission rates were 1,725,128, and 4,237,946 particle of size 0.3 µm.

The effects of filters are also studied on the model prediction based on their classes taking into account minimum efficiency reporting values (MERV), performance and breakthrough, mentioned in ASHRAE standard [18]. Four filter classes are studied, considering



Figure 2: EPC Ergotouch airborne particle

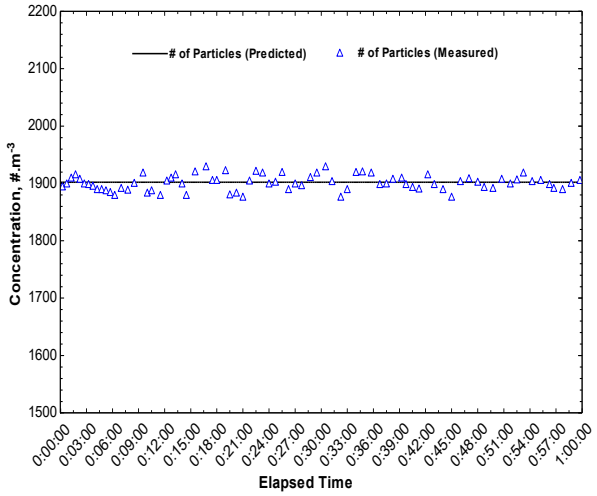


Figure 3: Particle concentrations in tested clean room

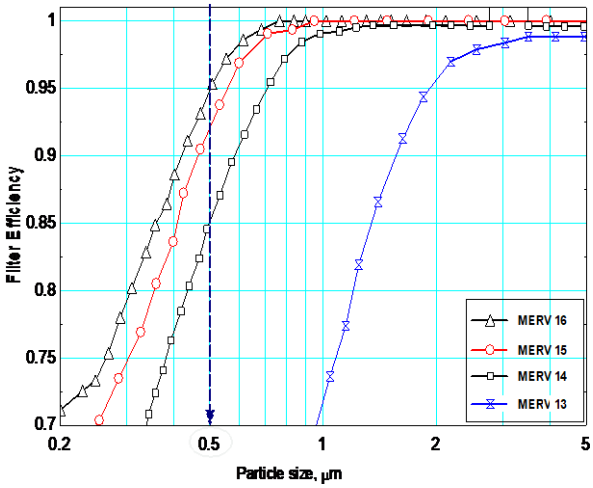


Figure 5: Filter efficiency according to MERV class

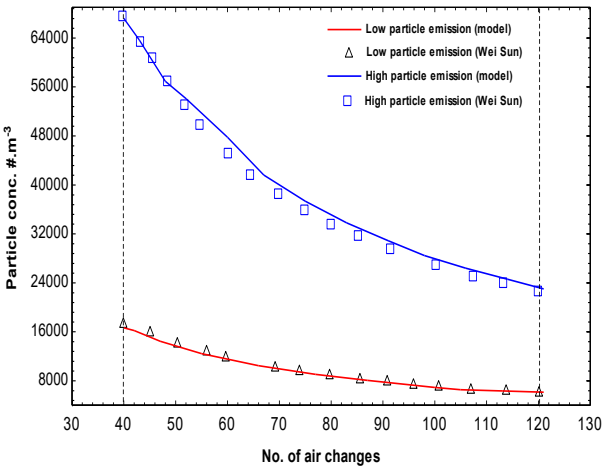


Figure 4: Effect of air change rate on 0.3 µm particle concentration with different particle emission rates

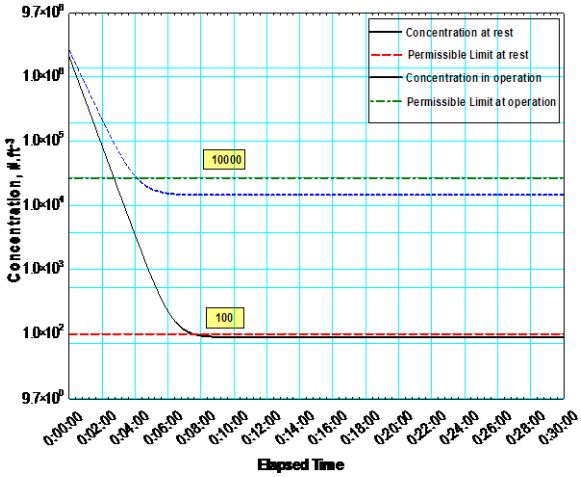


Figure 6: Particle concentrations at rest and at operation

the effects of MERV13, 14, 15 and 16 based on their performance as illustrated in *Figure 5*. The particle size 0.5 µm is our concern size which means that class numbers 14, 15, and 16 apply to this particle size while class number 13 does not recognize it.

5. Discussion

The model uses *Equations 1 and 2* to predict the concentration of particles inside area under study, which is classified as Class B according to the World Health Organization (WHO). The standard states 10,000 particles per cubic feet as the maximum permissible concentrations in operation and 100 particles at rest. The initial concentrations outside and inside are assumed to be the same and equal to 2.1E+6 particles per cubic feet, as the average values of three readings in *Table 1*.

The ventilation system operates according to the model configuration in *Figure 1*. The results in *Figure 6* illustrate the effect of the ventilation system on pollutant removal from area at rest and at operation, which gradually removes the pollutants from the area in about 8 minutes. *Figure 6* illustrates the particle prediction under both conditions, at rest and at operation. The predicted results should comply with the stated permissible values for class B 100 and 10,000 particles/ft^3 as stated in WHO [19], in both conditions and *Figure 6* shows that the predicted values are 89 particles at rest and 4912 particles in operation which are considered acceptable values in that specified conditions. So the values comply with the requirements of the regulatory standards.

5.1. Effect of filters classes

Two layers of filters are selected, one layer before area and the other with air cleaner within the area. The first layer has filter classes conforming to the standard by ASHRAE [18] from MERV 13 up to MERV16. Their performances are illustrated in *Figure 4* and their effects

are predicted on the area cleanness as shown in *Figure 7*. The other layer consists of one class of HEPA filters (H14). Filter classes MERV 16 and 15 are the suitable classes and the predictions are presented during operation and illustrate 4912 and 6011#/ft^3 but lowering the filter classes to MERV 14 and 13 they are not acceptable and exposes the area, the product, and the workers to higher pollutant concentrations as illustrated in *Figure 7*. All filters are selected as well to comply with filter specifications in international standards such as ASHRAE and WHO and are also specified in the facility design documentation of the facility. The results as well comply with requirements and do not exceed the permissible limits.

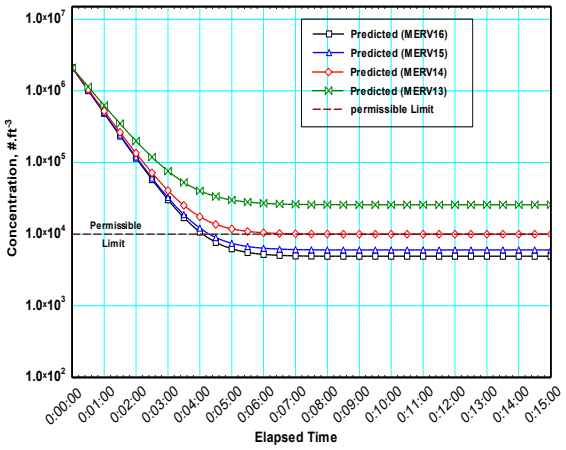


Figure 7: Particle concentration inside area, #/ft^3 with different filter classes

5.2. Effects of outside fresh air ratios and surface loading

The effects of outside fresh-air (O_A) ratios are studied in *Figure 8* depicting their influence on particle concentration in area under study. The fresh air is a challenge as it carries all pollutants from outside and deposited inside filters before polluting the area. Ratios are selected as 0.04, 0.07, 0.10 and 0.15 to study which values are preferable and satisfy the worker needs. The ratio 0.04 gives 4,912 #/ft^3 of pollutants As the ratio increases this means that the system challenges more airborne particles and a greater filtration load is imposed on the filters. Increasing the O_A to 0.07 results in 7,092 #/ft^3, and is still considered acceptable value. The ratio 0.10 is critical ratio as it results in 9281 #/ft^3 which locate on the standard acceptable border. Ratio 0.15 is not acceptable, because the particle concentration exceeds the standard class limit and results in 14,182 #/ft^3. Ventilation system can satisfy the class requirements in several recommended fresh air ratios when the area at operation as shown in *Figure 8*.

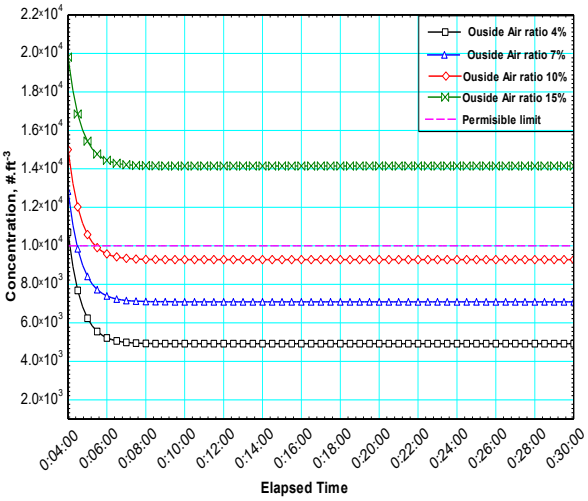


Figure 8: Particle concentration with different outside air ratio

Surface loading is resultant masses or number of particles deposited on each of the surface types divided by their respective surface areas as defined in the zone geometry section. Surface loading by resuspension is one of the advantages of ventilation system, as the particles settle on the surfaces (walls and floors) and the model considers it as removal process in calculation. We consider only the shift period (8 hrs). It does not reach steady state because the resuspension process is continuous as particles remain in the area and are removed only when the ventilation system stops.

Figure 9 shows the surface loading on the floor and air according to model *Equation 2*. Increasing total surface loading from 302280 to 554032 #/ft^2 during hours of shift (from 8:00 am to 18:00 pm) indicates the positive effect of the ventilation system, which reduces particle concentration in the area, while it loads these pollutants on the floor and surrounding walls.

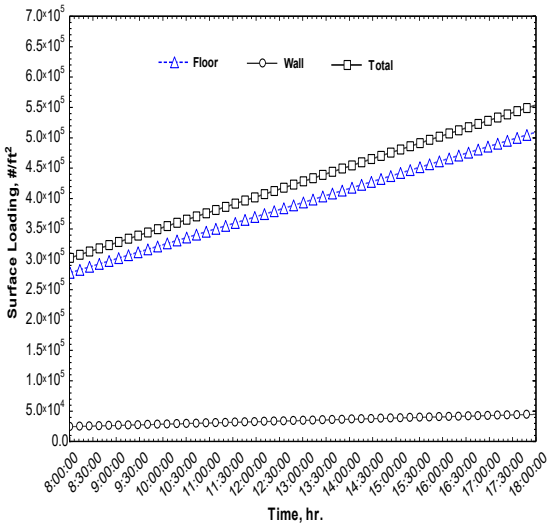


Figure 9: Number of particles deposited on each of the surface, #/ft^2

6. Conclusion

The simulation model is used to predict particle concentrations inside class B clean area in laboratory in

different cases, in operation and at rest using design parameters to assess whether these parameters satisfy the area requirements that comply with international standards for medical purposes. The cleanliness classification states that particle concentration must not exceed 100 #/ft^3 at rest and 10,000 #/ft^3 in operation. The model is validated under steady-state conditions in other facility showing good results. Validation against another model for particle size 0.3 µm as well is presented and shows good results. The predictions also demonstrate appropriate design parameters of ventilation system when compared with other design parameters to show the performance considering several influencing parameters such as filter classes from MERV class 13 to 16 with class H14 of HEPA (high efficiency particulate air) filters, and different fresh-air ratios of 0.04, 0.07, 0.10 and 0.15. Particle size is assumed 0.5µm with considered conservative assumptions such as deactivation characteristic and deposition phenomena with particle half-life. Wall and floor surface loading are also illustrated to express particle deposition on floor and side walls which is found reasonable in this dedicated class.

SYMBOLS

α: Contaminant or pollutant
C_α: Concentration of pollutant in air, [gm.m^{-3}]
Q: volumetric airflow rate, [m^3.s^{-1}]
L_{si}: Surface (i) that receives pollutants by loading, [gm.m^{-3}]
S: Source strength per unit time, [kg$_\alpha$/s]
V: Room (space) volume, m^{-3}
A_{si} : Surface area (i) exposed to deposition, m^2
v_{di} : Velocity of deposited particle on surface (i), m.s^{-1}
N_s : Amount of surfaces (Floor and walls)
η_{ac} : Efficiency of filtration,
K_d : Rate of deposition, [s^{-1}]
G: Rate of generation, [gm.s^{-1}]
A_{ri}: Surface area (i) exposed to resuspension, [m^2]
r_i : Rate of resuspension of particles on surface (i), [1/s]
P: Penetration factor of particle
R_α: Rate of removal via deposition of pollutants α from space air to surface per unit time t [kg$_\alpha$/s]
mult: Sink /source multiplier,
ctrl: Control value/ Schedule that source follows its emission in the space
T: time, s

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